California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Sponsored Legislation

SB 1307 (Ridley-Thomas) Electronic Pedigree

The bill contains additional provisions to improve implementation issues involving serialization and electronic pedigrees. Specifically, it specifies that the serialization number must be contained in the electronic pedigree, delays and staggers the implementation dates for e-pedigree compliance, allows for the grandfathering in of existing drug stock in the supply chain, and allows the board to establish criteria for inference requirements by regulation.

A copy of the language in its current form is found in **ATTACHMENT 1.**

Omnibus Provisions

SB 1779 contains several omnibus provisions for the board. With the exception to Business and Professions Code section 4161 the board previously approved all provisions. A motion and vote from the committee and board is necessary to formally approve the proposed language contained in Section 4161. Should the language not be approved as presented, board staff will follow up with the committee to ensure the necessary correction is made.

Use of Mobile Pharmacies

Section 4062 Furnishing Dangerous Drugs During an Emergency
This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership
This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

Pharmacist-in-Charge and Designated Representative in Charge

Amend Sections 4022.5, 4305, 4329, 4330 and Add section 4036.5.
The Board of Pharmacy is proposing changes to several sections of Business and Professions Code, clarifying the reporting requirements for documenting a change in the Pharmacist-In-Charge (PIC). The PIC is responsible for the overall operations in a pharmacy. There are also similar changes for the Designated Representative-in-Charge (DRC) of a wholesaler or veterinary food-animal drug retailer. This proposal would also define the term "pharmacist-in-charge" currently referenced throughout pharmacy law as well as place into statute the approval

process currently used by the board when evaluating a pharmacy application for approval of a proposed PIC or DRC.

General Omnibus Provisions

Amend Section 4059.5 - Who May order Dangerous Drugs or Devices, Exceptions
A technical change to this section clarifies that a designated representative must sign for and receive delivery of drugs by a wholesaler. This is important for accountability for drug purchases and receipt in wholesale operations.

Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
This section corrects a drafting error that occurred in Senate Bill 1307 (Chapter 857, statutes of 2004). The term "exemptee-in-charge was incorrectly updated to "representative-in-charge" and requires correction to the appropriate term "designated representative in charge."

Amend Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy
This section clarifies specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Amend Section 4161 – Nonresident Wholesaler: When License Required: Application
This section clarifies that any person that sells, brokers or distributes dangerous drugs or devices within California must be licensed.

Amend Health and Safety Code section 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature
This section requires an amendment requiring that a clinic that dispenses schedule III and schedule IV controlled substances must report weekly to CURES, similar to the requirements for pharmacies and prescribers who dispense controlled drugs as specified.

Corrections to Sections Referencing Prior Business and Professions Code §§ 4052

Omnibus changes based on recodification of Business and Professions Code section 4052

In 2006 Business and Professions Code section 4052 was recodified into four sections. The below B&PC and H&SC sections reference 4052 and require update.

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

A copy of the proposed language as presented to Senate Business and Professions is provided in **ATTACHMENT 2.**

The board approved additional omnibus provisions that are not included in this bill as they were considered controversial. The board can reconsider these provisions for inclusion in a future omnibus provision.

Amend Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

This section addresses the need to authorize the board to automatically inactivate a pharmacist license when a pharmacist, who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation. This authority already exists when a pharmacist fails to certify completion of continuing education as part of the renewal application.

Section 4362 – Entry Into Pharmacists Recovery Program (PRP)

This section specifies the administrative co-pay participants pay as part of their participation in the PRP. The board subsidizes the administrative cost, however it requires the participant to also pay a portion of the administrative costs of the program. The current administrative co-pay, $75.00, is set by contract only. The board has not sought a change in this co-pay in over 10 years, and has continually absorbed the additional monthly administrative fee, currently about $230/month per participant.

This section allows the board the ability to waive a participant's co-pay for demonstrated financial hardship.

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STATE AND CONSUMERS AFFAIRS AGENCY
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ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Legislation of Interest

Provided in this packet are copies of bills and analyses of legislation impacting the practice of pharmacy or the board's jurisdiction (**ATTACHMENT 3**). A brief summary of the measure is included below. Some Items were previously considered by the board and the Board Position noted.

If the committee so chooses, it can reconsider positions previously taken as well as take positions on new legislation to forward to the board for consideration and action at the July 2008 Board Meeting.

1. AB 501 (Swanson and Hancock) Pharmaceutical Devices

Require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to provide upon request of a consumer, a postage prepaid mail-back sharps container for safe disposal of the used device or a sharps container for storage and transport to a sharps consolidation location.

Board Position: Support
Status: Senate – Third Reading

2. AB 865 (Davis) State Agencies: Live Customer Service Agents

Require specified state agencies to answer incoming phone calls within 10 rings by either a live customer service agent or automated telephone answering equipment which then must include an option to reach a live customer service agent.

Board Position: Neutral
Status: Senate - Third Reading

3. AB 1394 (Krekorian) Counterfeit: Trademarks

Remove the requirement that the sale of counterfeit mark be intentional and also make it a misdemeanor or a felony for a business entity to willfully manufacture, sell or knowingly possess for sale any counterfeit registered trademark.

Board Position: Support
Status: Senate Appropriations Committee

4. AB 1436 (Hernandez) Nurse Practitioners

Revise the educational requirements for qualification or certification as a nurse practitioner and would require a nurse practitioner to be certified by a nationally recognized body approved by the Board of Registered Nursing. Expand the scope of practice to allow a nurse practitioner to perform comprehensive health care services as specified and is authorized to admit and discharge patients from health facilities, change a treatment regimen and initiate an emergency procedure in collaboration with healing arts practitioners.

Board Position: None
Status: Senate Business, Professions and Economic Development Committee

5. AB 1574 (Plescia) Surgical clinics: licensure

Would expand the board's licensing authority to issue a clinic permit to surgical clinics to such clinics that Medicare certified or accredited by an recognized agency and require the board to perform periodic inspections and establish a self-assessment requirement.

Board Position: None
Status: Senate – Second Reading

6. AB 1587 (De La Torre) Personal Information: Pharmacy

Exclude from the definition of marketing a written communication or written message provided to a pharmacy patient by a pharmacist or pharmacy personnel that meets specified conditions.

Board Position: None
Status: Senate Judiciary Committee – Not heard

According to the sponsor, this bill will not be moved this year. As such a copy of the bill and analysis is not provided.

7. AB 2756 (Duvall) Pharmacists: furnishing drugs during an emergency

Specify that for purposes of furnishing dangerous drugs and devices during an emergency, a pharmacist is not required to await a declaration of emergency as long the declaration is reasonably anticipated due to the severity of the emergency or natural disaster.

Board Position: None
Status: Assembly Appropriations Committee

8. SB 963 (Ridley-Thomas) Regulatory Boards: Sunset Review

Replaces the process whereby a sunsetted board becomes a bureau in the Department of Consumer Affairs (DCA) with reconstitution of the board's members, and specifies other reporting requirements.

Board Position: None
Status: Assembly Appropriations Committee

9. SB 1270 (Cedillo) Pharmacy: dangerous drug and devices pedigree

Create an Electronic Pedigree Taskforce to provide the board with updates regarding industry readiness on the implementation of the pedigree requirements as well as submit an annual report to the board and specified legislative committees.

Board Position: None
Status: Assembly Appropriations Committee

10. SB 1441 (Ridley-Thomas) Healing Arts Practitioners: Substance Abuse

Create the Substance Abuse Coordination Committee with the Department of Consumer Affairs to develop uniform and specific standards that each healing arts board would be required to use in dealing with substance-abusing licensees.

Board Position: None
Status: Assembly Appropriations Committee

Inactive Bills

Below is a list of inactive/dead bills that the board previously discussed.

1. AB 1947 (Emmerson) Pharmacy Technicians

Would increase the minimum requirements for licensure as a pharmacy technician to include both certification by the Pharmacy Technician Certification Board as well as either completion of a technician training program or a specified associate's degree. In addition, would require pharmacy technicians to complete 20 hours of continuing education each renewal cycle.

Board Position: None
Status: Hearing Cancelled at the request of the author.

2. AB 2122 (Plescia) Surgical clinics: licensure

Would define the operational, staffing and procedural standards for surgical clinics and would require the board to perform periodic inspections at least once every three years.

Board Position: None
Status: Assembly Appropriations Committee – Suspense File

3. AB 2516 (Mendoza) Prescriptions: electronic transmission

Would require a prescriber to ensure that any prescription issued shall be electronically transmitted to the patient's pharmacist of choice, except as specified.

Board Position: None
Status: Failed Deadline

4. AB 2643 (Cook) Drugs and Devices

Would replace references to the United State Pharmacopoeia in relevant sections of the Business and Professions Code, Health and Safety Code, Insurance Code, Penal Code, Public Resources Code and Welfare and Institutions Code.

Board Position: None
Status: Failed Deadline

5. SB 1096 (Calderon) Medical Information

Would allow a pharmacy under specified conditions, to mail specified written communications to a patient, without the patient's authorization.

Board Position: Oppose
Status: Failed Passage – Assembly Health Committee

6. SB 1504 (Ridley-Thomas) Antiepileptic drug products: substitution.

Would prohibit a pharmacist from filling a prescription for an antiepileptic drug that is prescribed by its trade, brand or generic name from substituting a drug product without prior notification of the prescriber and a signed consent of the patient or the patient's agent.

Board Position: None
Status: Failed Deadline

7. SB 1594 (Steinberg) Bleeding Disorders Clotting Products

Imposes requirements on providers of blood clotting products for home use that are used to treat hemophilia and other bleeding disorders.

Board Position: None
Status: Failed Deadline

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ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Awaiting Notice

BOARD APPROVED REGULATIONS – AWAITING PUBLIC NOTICE

1. Proposed Repeal of 16 CCR §§ 1716.1 and 1716.2 and amendment to 16 CCR § 1751-1751.8 and adoption of 16 CCR §§1735-1735.8

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

At the January 2008 board meeting, the board conducted a regulation hearing to hear testimony about the regulation proposal that establishes requirements for pharmacies that compound medications. As a result of this regulation hearing, the board voted to complete a 15-day notice with revised language to address some of the written comments received and oral testimony provided.

Given the significant amount of comments submitted and testimony provided, staff recommended and the board voted to withdraw the rulemaking to allow time to further refine the draft language.

Staff planned to notice the revised rulemaking in advance of the July 2008 Board Meeting, however because of conflicting priorities within the department's legal office, we were unable to submit by the deadline to allow for action by the board in July. Staff will notice the rulemaking for action by the board at the October 2008 Board Meeting. A copy of the revised language is included in **ATTACHMENT 4.**

2. Proposed Addition to 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the

designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

A copy of the draft language and form is included in **ATTACHMENT 5.** Staff anticipate initiating the 45-day comment period in advance of the July Board Meeting to allow for action by the board at the July 2008 Meeting.

3. Proposed Amendment to 16 CCR §1780 – Update the USP Standards Reference Material

CCR 1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity standards. The USP Standards is updated and published annually. Consequently, this section requires an amendment to amend Section 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

At the April 2007 Legislation and Regulation Committee Meeting, the committee was advised to review the updates made in the USP Standards Reference Material referenced in the proposed language to ensure that the board was fully aware of and in support of the USP changes. Given this, board staff did not include this proposed regulation change, but rather is seeking input from the pharmacy industry to highlight potential problems with referencing the 2005 edition of the USP Standards Reference Material. At the June 2007 committee meeting, Dr. Schell offered to facilitate a taskforce to review the USP Standards Reference Material.

To date board staff has not received any additional information or concerns about pursuing this change and is seeking guidance from the committee on whether to pursue this regulation change.

4. Proposed Adoption of 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

At the July 2007 Board Meeting, the board voted to move this proposal.

A copy of the language is provided in **ATTACHMENT 6.**

5. Proposed Amendment to 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality.

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR 1721 and 1723.1 that would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

A copy of the language is provided in **ATTACHMENT 7.**

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To: Legislation and Regulation Committee

From: Staff

Subject: Board Adopted Regulations

At the April 2008 board meeting, the board voted to adopt a regulation change to amend Title 16 CCR 1760 – Disciplinary Guidelines. During discussion at this board meeting, counsel recommended that the board strengthen the response to comments submitted during the written comment period. Staff is awaiting further explanation from counsel for inclusion in the rulemaking. Upon receipt of this information, staff will move forward to compile the rulemaking file to submit for administrative review.

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To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations – Proposed Language for Committee Consideration

Following is draft language for committee consideration. Subsequent to the committee's recommendation, language could be considered by the full board at the July 2008 Board Meeting.

Ethics Course for Pharmacists

At the October 2007 Board Meeting, the board voted to pursue a regulation proposal to develop an ethics course for pharmacists, modeled after the program used by the Medical Board of California. Staff is working with the Institute for Medical Quality to define the scope of the proposal.

ATTACHMENT 8 contains the draft language for committee consideration. Based on the results of the committee's recommendation, language could be considered by the full board at the July 2008 Board Meeting.

16 CCR 1715 – Self Assessment Forms

Board staff will begin work to update the Self-Assessment forms to incorporate changes made in pharmacy law since its last revision in 2007. As these forms are incorporated by reference in section 1715, the board must pursue a regulation change to require use of the new form.

ATTACHMENT 9 contains the draft language for committee consideration. Based on the results of the committee's recommendation, language could be considered by the full board at the July 2008 Board Meeting.

Attachment 1

SB 1307 (Ridley-Thomas) Electronic Pedigree

AMENDED IN ASSEMBLY JUNE 17, 2008

AMENDED IN SENATE MAY 23, 2008

AMENDED IN SENATE APRIL 29, 2008

AMENDED IN SENATE MARCH 25, 2008

SENATE BILL No. 1307

Introduced by Senator Ridley-Thomas

February 20, 2008

An act to amend Sections 4034 and 4163 of, to add Sections 4034.1, 4163.2, ~~and 4163.3~~ *4163.3, and 4163.4* to, and to repeal and add Section 4163.5 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, as amended, Ridley-Thomas. Pharmacy: pedigree.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy, in the Department of Consumer Affairs. Under existing law, on and after January 1, 2009, pedigree means an electronic record containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. On and after January 1, 2009, existing law prohibits a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree. Existing law, on and after January 1, 2009, requires that a pedigree include certain information, including, but not limited to, the source of the dangerous

drug and the trade or generic name of the drug. Existing law exempts specified transactions from the pedigree requirement, and authorizes the board to extend the January 1, 2009, compliance date to January 1, 2011, in specified circumstances. Existing law makes it a crime to knowingly violate the Pharmacy Law.

This bill would instead, on and after January 1, 2011, define a pedigree, *as specified,* and would require a pedigree to include a specified unique identification number. The bill would also require the board to immediately require the use of federally required standardized numerical identifiers and standardized data elements of a pedigree record if federal standards in that regard are developed under federal law.

The bill would instead prohibit a wholesaler, on and after January 1, ~~2012~~ *2015*, or a pharmacy, on and after July 1, ~~2012~~ *2015*, from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree, except as specified. *The bill would require wholesalers and pharmacies, between January 1, 2011, and December 31, 2014, to initiate steps to accept and pass electronic pedigrees for all dangerous drugs subject to the pedigree requirements to enable full readiness to meet the above requirement.* The bill would delete the board's authority to extend these compliance dates. The bill would require a manufacturer of a dangerous drug distributed in California to designate certain percentages of the drugs that it manufactures to comply with the pedigree requirement by specified dates, and to notify the board of the drugs so designated and of the technology to be used to meet that requirement. The bill would also exempt specified additional transactions from the pedigree requirement.

The bill would authorize a manufacturer, wholesaler, or pharmacy in possession of dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements to designate these drugs as not subject to the requirements by preparing a specified written declaration under penalty of perjury, *which would be considered trade secrets and kept confidential by the board.* The bill would~~, for up to 18 months following the operative date of the pedigree requirements,~~ authorize specified dangerous drugs to be purchased, sold, acquired, returned, or otherwise transferred, without meeting the pedigree requirements if the transfer complies with specified requirements~~, including a written declaration under penalty of perjury stating that the specified dangerous drug met certain requirements~~. Because a knowing

violation of the bill's provisions would be a crime under the Pharmacy Law and because the bill would expand the crime of perjury, the bill would impose a state-mandated local program.

The bill would require the board to promulgate regulations defining the circumstances ~~where the board deems it appropriate for manufacturers, wholesalers, or pharmacies, to~~ *under which participants in the distribution chain may* infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, *if certain standard operating procedures are complied with and made available for the board to review. The bill would require board regulations to specify liability associated with accuracy of product information and pedigree using inference.* The bill would declare the intent of the Legislature in this regard.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4034 of the Business and Professions Code is amended to read:

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, *repackagers,* or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(5) The unique identification number described in subdivision (i).

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug. For purposes of this section, the "smallest package or immediate container" of a dangerous drug shall be the smallest unit made by the manufacturer for sale to the pharmacy or other person furnishing, administering, or dispensing the drug.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are exempt from the pedigree requirement created by this section:

(1) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(2) (A) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.

(B) The exemption in this paragraph shall expire and be inoperative on January 1, 2012, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, 2013. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.

(3) (A) A sale, trade, or transfer of a radioactive drug, as defined in Section 1708.3 of Title 16 of the California Code of Regulations, between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state.

(B) The exemption in this paragraph shall remain in effect unless the board, no earlier than the date that is two years after the compliance date for manufacturers set forth in subdivision (k) of Section 4034 or Section 4163.5, determines after consultation with the Radiologic Health Branch of the State Department of Public Health that the risk of counterfeiting or diversion of a radioactive drug is sufficient to require a pedigree. Two years following the

date of any such determination, this paragraph shall become inoperative.

(4) The sale, trade, or transfer of a dangerous drug that is labeled by the manufacturer as "for veterinary use only."

(5) The sale, trade, or transfer of compressed medical gas. For purposes of this section, "compressed medical gas" means any substance *in its gaseous or cryogenic liquid form* that meets medical purity standards and has application in a medical *or homecare* environment, including, but not limited to, oxygen and nitrous oxide.

(6) The sale, trade, or transfer of solutions. For purposes of this section, "solutions" means any of the following:

(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.

(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

(j) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(k) This section shall become operative on January 1, 2011. However, the board may extend the date for compliance with this section and Section 4163 in accordance with Section 4163.5.

SEC. 2. Section 4034.1 is added to the Business and Professions Code, to read:

4034.1. Notwithstanding anything to the contrary in Section 4034 or 4163, if federal standards are developed pursuant to Section 505D of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355e) regarding the identification, validation, authentication, tracking, and tracing of prescription drugs, and with respect to a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing and repacking at the package or pallet level, the board shall immediately issue emergency regulations or take other action within 30 days to require use of the federally identified standardized numerical identifier as the unique identification number otherwise required by subdivision (i) of Section 4034. In addition, if the federal standards developed pursuant to the above-referenced section of the federal act include a specification of standardized data elements of a pedigree record, those data elements shall be automatically substituted by the board for those otherwise required by subdivision (b) of Section 4034. Notwithstanding subdivision (k) of Section 4034, the requirements of this section with respect to the use of standardized numerical identifiers and specification of standarized data elements shall be in effect immediately upon the board's action to implement this section.

SEC. 3. Section 4163 of the Business and Professions Code is amended to read:

4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) From January 1, 2011, to December 31, 2014, inclusive, wholesalers and pharmacies shall initiate steps to accept and pass electronic pedigrees for all dangerous drugs subject to the

requirements of Section 4034, in order to enable full readiness to comply with subdivisions (d) to (g), inclusive.

~~(c)~~

(d) Except as otherwise provided in Section 4163.5, commencing on January 1, ~~2012~~ *2015*, a wholesaler may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

~~(d)~~

(e) Except as otherwise provided in Section 4163.5, commencing on January 1, ~~2012~~ *2015*, a wholesaler may not acquire a dangerous drug without receiving a pedigree.

~~(e)~~

(f) Except as otherwise provided in Section 4163.5, commencing on July 1, ~~2012~~ *2015*, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

~~(f)~~

(g) Except as otherwise provided in Section 4163.5, commencing on July 1, ~~2012~~ *2015*, a pharmacy may not acquire a dangerous drug without receiving a pedigree.

SEC. 4. Section 4163.2 is added to the Business and Professions Code, to read:

4163.2. (a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the National Drug Code Directory ~~number and batch number and the dates of manufacture~~ *lot number* for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. *Information contained in these*

declarations shall be considered trade secrets and kept confidential by the board.

~~(b) (1) For up to 18 months following the operative date of the pedigree requirements, any~~

(b) Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.

~~(2) Any transfer of a dangerous drug without meeting the pedigree requirements shall be accompanied by a written declaration made under penalty of perjury by a responsible party of the transferring entity or person stating that the dangerous drug, identified by its National Drug Code Directory number and batch number and date of manufacture, met the requirements of subdivision (a) and the written declaration prepared pursuant to subdivision (a) shall be attached to this written declaration.~~

~~(3) Both the transferring and receiving parties shall retain for a period of three years and make available for inspection by the board a copy of each written declaration.~~

~~(4) The board may, by regulation, further specify the requirements and procedures for these transfers and the necessary documentation.~~

~~(5) The board may, by regulation, further extend beyond 18 months the period for transfers of nonpedigreed drugs, either for all drugs or for specified categories or subcategories of drugs.~~

SEC. 5. Section 4163.3 is added to the Business and Professions Code, to read:

4163.3. (a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, *and to facilitate efficiency and safety in the distribution chain,* the board shall, by regulation, define the circumstances under which ~~the board deems it appropriate for~~

participants in the distribution chain ~~to~~ *may* infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.

(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

SEC. 6. Section 4163.4 is added to the Business and Professions Code, to read:

4163.4. (a) All units of dangerous drug in the possession of a wholesaler or pharmacy, for which the manufacturer does not hold legal title on the effective date of the pedigree requirement set forth in Section 4163.5, shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163. However, if any units of those drugs are subsequently returned to the manufacturer, they shall be subject to the pedigree requirements if the manufacturer distributes those units in California.

(b) All units of dangerous drug manufactured in California but distributed outside the state for dispensing outside the state shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163 at either the time of initial distribution or in the event that any of those units are subsequently returned to the manufacturer.

~~SEC. 6.~~

SEC. 7. Section 4163.5 of the Business and Professions Code is repealed.

~~SEC. 7.~~

SEC. 8. Section 4163.5 is added to the Business and Professions Code, to read:

4163.5. (a) The Legislature hereby finds and declares that:

(1) The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

(2) At the same time, it is recognized that the process of implementing serialized electronic pedigree for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while drug manufacturers implement these requirements.

(b) ~~On or before January 1, 2010~~ *Before January 1, 2011*, each manufacturer of a dangerous drug to be distributed in California shall designate drugs representing a minimum of 20 percent of the drugs, generic or single source, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with *the January 1, 2011, deadline of* the state's serialized pedigree requirement set forth in Sections 4034 and 4163. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.

(c) ~~On or before January 1, 2011~~ *Before January 1, 2013*, each manufacturer shall designate a minimum of an additional 30 percent of the drugs for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, ~~2012~~ *2013*. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.

(d) ~~On or before January 1, 2012~~ *Before January 1, 2015*, each manufacturer shall designate a minimum of an additional 50 percent of the drugs for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, ~~2013~~ *2015*. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.

~~(e) All new dangerous drugs that are approved for sale on or after January 1, 2011, shall be subject to the serialized electronic pedigree requirements set forth in Sections 4034 and 4163 when introduced on the market, and shall not be included in a manufacturer's yearly implementation quota.~~

(e) For purposes of designating drugs to be serialized as required by subdivisions (b), (c), and (d), manufacturers shall select from any of the following measures:

(1) Unit volume.

(2) Product package (SKU) type.

(3) Drug product family.

(f) Drugs not subject to compliance with the pedigree requirements set forth in Sections 4034 and 4163 under this section shall not be subject to the provisions of subdivisions (c), (d), (e), and (f) of Section 4163.

~~SEC. 8.~~

SEC. 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Attachment 2

SB 1779 (Committee on Business, Professions and Economic Development)
Healing Arts, Omnibus

AMENDED IN ASSEMBLY JUNE 12, 2008

AMENDED IN ASSEMBLY JUNE 5, 2008

AMENDED IN SENATE MAY 5, 2008

AMENDED IN SENATE APRIL 16, 2008

SENATE BILL No. 1779

Introduced by Committee on Business, Professions and Economic Development (Senators Ridley-Thomas (Chair), Aanestad, Calderon, Corbett, Denham, Florez, Harman, Simitian, and Yee)

March 13, 2008

An act to amend Sections 128.5, 149, 683, 733, 800, 801, 803, 2089.5, 2096, 2102, 2107, 2135, *2168.4,* 2175, 2307, 2335, 2486, 2488, 2570.5, *2570.7,* 2570.6, 2760.1, 3503, 3517, 3518, 3625, 3633.1, 3635, 3636, 3685, 3750.5, 3753.5, 3773, 4022.5, 4027, 4040, 4051, 4059.5, 4060, 4062, 4076, 4081, 4110, 4111, 4126.5, *4161,* 4174, 4231, 4301, 4305, 4329, 4330, 4980.03, 4980.30, 4980.43, 4982, 4989.54, 4992.3, 4996.2, 4996.17, 4996.18, and 4996.23 of, to amend and renumber Section 2570.185 of, to add Sections *2169,* 2570.36, 4036.5, 4980.04, and 4990.09 to, and to repeal Sections 2172, 2173, 2174, 4981, 4994.1, 4996.20, and 4996.21 of, the Business and Professions Code, to amend Section 8659 of the Government Code, and to amend Sections 11150 and 11165 of the Health and Safety Code, relating to healing arts, *and making an appropriation therefor.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1779, as amended, Committee on Business, Professions and Economic Development. Healing arts.

(1) Under existing law, if, upon investigation, a specified state regulatory agency has probable cause to believe that a person is

(b) The licensee shall cooperate in providing additional information as requested by the board. If a licensee fails to provide the requested information within 30 days, the license shall become inactive until the information is received.

~~SEC. 37.~~

SEC. 40. Section 4022.5 of the Business and Professions Code is amended to read:

4022.5. (a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.

(b) "Designated representative-in-charge" means a designated representative or a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

(c) This section shall become operative on January 1, 2006.

~~SEC. 38.~~

SEC. 41. Section 4027 of the Business and Professions Code is amended to read:

4027. (a) As used in this chapter, the terms "skilled nursing facility," "intermediate care facility," and other references to health facilities shall be construed with respect to the definitions contained in Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code.

(b) As used in Section 4052.1, "licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility, as defined in Section 1250 of the Health and Safety Code, operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(c) As used in Section 4052.2, "health care facility" means a facility, other than a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of the Health and Safety Code, or by an organization under common

ownership or control of the health care service plan; "licensed home health agency" means a private or public organization licensed by the State Department of Health Services pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code, as further defined in Section 1727 of the Health and Safety Code; and "licensed clinic" means a clinic licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2 of the Health and Safety Code.

(d) "Licensed health care facility" or "facility," as used in Section 4065, means a health facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or by an organization under common ownership or control with the health care service plan.

~~SEC. 39.~~

SEC. 42. Section 4036.5 is added to the Business and Professions Code, to read:

4036.5. "Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

~~SEC. 40.~~

SEC. 43. Section 4040 of the Business and Professions Code is amended to read:

4040. (a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to either Section 4052.1 or 4052.2.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to either Section 4052.1 or 4052.2 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor,

while acting within the scope of his or her license, may have to prescribe a device.

~~SEC. 41.~~

SEC. 44. Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052.1, 4052.2, or 4052.3, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

~~SEC. 42.~~

SEC. 45. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the

pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name

and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall become operative on January 1, 2006.

~~SEC. 43.~~

SEC. 46. Section 4060 of the Business and Professions Code is amended to read:

4060. No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either Section 4052.1 or 4052.2. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

~~SEC. 44.~~

SEC. 47. Section 4062 of the Business and Professions Code is amended to read:

4062. (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible.

Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:

(1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.

(2) The mobile pharmacy retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist is on the premises and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The mobile pharmacy is located within the declared emergency area or affected areas.

(6) The mobile pharmacy ceases the provision of services within 48 hours following the termination of the declared emergency.

~~SEC. 45.~~

SEC. 48. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2

orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

~~SEC. 46.~~

SEC. 49. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be

at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall become operative on January 1, 2006.

~~SEC. 47.~~

SEC. 50. Section 4110 of the Business and Professions Code is amended to read:

4110. (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy.

When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

(c) The board may allow the temporary use of a mobile pharmacy when a pharmacy is destroyed or damaged, the mobile pharmacy is necessary to protect the health and safety of the public, and the following conditions are met:

(1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.

(2) The mobile pharmacy is under the control and management of the pharmacist-in-charge of the pharmacy that was destroyed or damaged.

(3) A licensed pharmacist is on the premises while drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction or damage of the pharmacy and an expected restoration date.

(6) Within three calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration of the permanent pharmacy.

(7) The mobile pharmacy is not operated for more than 48 hours following the restoration of the permanent pharmacy.

~~SEC. 48.~~

SEC. 51. Section 4111 of the Business and Professions Code is amended to read:

4111. (a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to Section 4052.1 or 4052.2.

~~SEC. 49.~~

SEC. 52. Section 4126.5 of the Business and Professions Code is amended to read:

4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

SEC. 53. Section 4161 of the Business and Professions Code is amended to read:

4161. (a) A person located outside this state that *(1)* ships, *sells,* mails, or delivers dangerous drugs or dangerous devices into this state *or (2) sells, brokers, or distributes dangerous drugs or devices within this state* shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, *selling,* mailing, or delivering dangerous drugs or dangerous devices to a site located in this state *or selling, brokering, or distributing dangerous drugs or devices within this state.*

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, *sold,* mailed, or delivered to a site located in this state *or sold, brokered,*

or distributed within this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state *or within this state*, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(*l*) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

~~SEC. 50.~~

SEC. 54. Section 4174 of the Business and Professions Code is amended to read:

4174. Notwithstanding any other provision of law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, or 4052.3.

~~SEC. 51.~~

SEC. 55. Section 4231 of the Business and Professions Code is amended to read:

4231. (a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the two years preceding the application for renewal.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

(d) If, as part of an investigation or audit conducted by the board, a pharmacist fails to provide documentation substantiating the completion of continuing education as required in subdivision (a), the board shall cancel the active pharmacist license and issue an inactive pharmacist license in its place. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

~~SEC. 52.~~

SEC. 56. Section 4301 of the Business and Professions Code is amended to read:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall

include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(*l*) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not

involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

(t) This section shall become operative on January 1, 2006.

~~SEC. 53.~~

SEC. 57. Section 4305 of the Business and Professions Code is amended to read:

4305. (a) Failure by any pharmacist to notify the board in writing that he or she has ceased to act as pharmacist-in-charge of a pharmacy, or by any pharmacy to notify the board in writing that a pharmacist-in-charge is no longer acting in that capacity, within the 30-day period specified in Sections 4101 and 4113shall constitute grounds for disciplinary action.

(b) Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action.

(c) Any person who has obtained a license to conduct a pharmacy, who willfully fails to timely notify the board that the pharmacist-in-charge of the pharmacy has ceased to act in that capacity, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist subject to the supervision and management of a responsible pharmacist-in-charge,

shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

~~SEC. 54.~~

SEC. 58. Section 4329 of the Business and Professions Code is amended to read:

4329. Any nonpharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous drugs except as otherwise provided in this chapter, is guilty of a misdemeanor.

~~SEC. 55~~

SEC. 59. Section 4330 of the Business and Professions Code is amended to read:

4330. (a) Any person who has obtained a license to conduct a pharmacy, who fails to place in charge of the pharmacy a pharmacist, or any person, who by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs, in his or her pharmacy, except by a pharmacist, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(b) Any pharmacy owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor.

~~SEC. 56.~~

SEC. 60. Section 4980.03 of the Business and Professions Code is amended to read:

4980.03. (a) "Board," as used in this chapter, means the Board of Behavioral Sciences.

(b) "Intern," as used in this chapter, means an unlicensed person who has earned his or her master's or doctor's degree qualifying him or her for licensure and is registered with the board.

(c) "Trainee," as used in this chapter, means an unlicensed person who is currently enrolled in a master's or doctor's degree program, as specified in Section 4980.40, that is designed to qualify him or her for licensure under this chapter, and who has completed no less than 12 semester units or 18 quarter units of coursework in any qualifying degree program.

(d) "Applicant," as used in this chapter, means an unlicensed person who has completed a master's or doctoral degree program,

Attachment 3

- Bills
- Analyses

AMENDED IN SENATE JUNE 19, 2008

AMENDED IN SENATE JUNE 11, 2008

AMENDED IN SENATE MAY 6, 2008

AMENDED IN SENATE MARCH 13, 2008

AMENDED IN ASSEMBLY JANUARY 29, 2008

AMENDED IN ASSEMBLY JANUARY 9, 2008

AMENDED IN ASSEMBLY JANUARY 7, 2008

AMENDED IN ASSEMBLY JUNE 21, 2007

AMENDED IN ASSEMBLY APRIL 30, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 501

Introduced by Assembly Members Swanson and Hancock (Coauthor: Assembly Member Dymally)

February 20, 2007

An act to add Section 118288 to the Health and Safety Code, relating to pharmaceutical devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 501, as amended, Swanson. Pharmaceutical devices.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Under existing law, certain items, such as home-generated sharps waste, as defined, are specifically excluded from the definition of medical waste. The act prohibits, on or

after September 1, 2008, a person from knowingly placing home-generated sharps waste in certain types of containers, provides that home-generated sharps waste is to be transported only in a sharps container, as defined, or other container approved by the department or local enforcement agency, and requires this waste to only be managed at specified locations consistent with existing law.

This bill would require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to arrange to provide, upon request from a consumer, a postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the department or a sharps container for the safe storage and transport of sharps to a sharps consolidation location approved by the department or a clinic, physician, or pharmacy that accepts home-generated sharps waste, as defined, along with concise information on safe disposal alternatives and options for sharps *and notice of the act's above described prohibition, that commences September 1, 2008.* As ~~an alternative~~ *a means of meeting these above described requirements*, the manufacturer may provide the consumer with a coupon that can be exchanged for, or a toll-free telephone number or Web site that can direct the patient to a supplier of, a qualified sharps container. This bill would also prohibit the manufacturer, or any person or agent with whom the manufacturer contracts, from using information collected for this purpose for any other purpose.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) An estimated 1 million Californians must self-inject prescription medications annually to treat a broad range of serious health problems.

(b) The use of prefilled syringes, prefilled pens, and other prefilled devices with needles is an effective method of prescription drug delivery and is expected to increase significantly in the future. Prefilled syringes, prefilled pens, and other prefilled devices with needles are clearly identified and linked to specific pharmaceutical

manufacturers for the provision of their product to California residents.

(c) The increased use of prefilled syringes, prefilled pens, and other prefilled devices with needles will generate millions of home-generated sharps each year. Prefilled pen devices are being used for the treatment of some of the most serious health conditions such as HIV/AIDS, hepatitis C, and many other diseases. If improperly disposed in solid waste and recycling containers these needles will result in significant public health risks.

(d) The Legislature has found that sharps mail-back programs utilizing containers and packaging approved by the United States Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that the cooperative efforts of the pharmaceutical industry are needed to develop a safe needle disposal system for California.

SEC. 2. Section 118288 is added to the Health and Safety Code, to read:

118288. (a) Upon request of a consumer who has been dispensed a prefilled syringe, prefilled pen, or other prefilled injection device for administration at home ~~that meets the definition of home-generated sharps waste in Section 117671,~~ a pharmaceutical manufacturer shall arrange to provide the consumer with either of the following:

(1) A postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the State Department of Public Health.

(2) A sharps container for the safe storage of, and transport to, a sharps consolidation location that is approved by the State Department of Public Health or to a clinic, physician, or pharmacy that accepts home-generated sharps waste.

(3) In addition to providing an appropriate sharps container, the manufacturer shall provide information on safe disposal alternatives and options for sharps *and notice to the consumer that effective September 1, 2008, California law prohibits a person from knowingly disposing of home-generated sharps in any container used for the collection of solid waste, recyclable materials, or green waste or for the commercial collection of solid waste or recyclable materials from business establishments.*

(b) For purposes of this section, "sharps container" has the same meaning as in Section 117750.

(c) As ~~an alternative to~~ *a means of* meeting the requirements of subdivision (a), a manufacturer may do either of the following:

(1) Supply a coupon, either to be delivered to the patient or with the device when it is dispensed, that may be exchanged for a sharps container that meets the requirements of paragraph (1) or (2) of subdivision (a).

(2) Provide a toll-free telephone number or Web site, noted on the packaging containing the device, that directs the patient to a supplier of sharps containers that meets the requirements of paragraph (1) or (2) of subdivision (a).

(d) A manufacturer shall not use or disclose information that it receives in the course of complying with this section for any other purpose, including, but not limited to, marketing, without the written consent of the consumer. This prohibition shall apply to any person or agent with whom the manufacturer contracts or otherwise makes arrangements to carry out the requirements of this section.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 501 **VERSION: As amended June 19, 2008**

AUTHOR: Swanson **SPONSOR: Alameda County Board of Supervisors**

POSITION: Support

SUBJECT: Pharmaceutical devices: hypodermic needle and syringe disposal

EXISTING LAW:

1. Prohibits the disposal of a hypodermic needle or syringe on the grounds of a playground, beach, park, or any public or private elementary school, vocational, junior high or high school.
2. States that a person who knowingly violates this section is guilty of a misdemeanor.
3. Requires that on or after September 1, 2008, no person shall knowingly place home-generated sharps waste in any of the following containers:
   a. Any container used for collection of solid waste or recyclable materials, or greenwaste
   b. Any container used for the commercial collection of solid waste or recyclable materials from business establishments
   c. Any roll-off container used for collectables of solid waste, construction, and demolition debris, greenwaste or other recyclable materials
4. Requires that on or after September 1, 2008, home-generated sharps waste shall be transported only in a sharps container, or other containers approved by the enforcement agency and shall only be managed at any of the following:
   a. A household hazardous waste facility
   b. A "home generated sharps consolidation point"
   c. A medical waste generator's facility
   d. A facility though the use of an approved medical waste mail-back container

THIS BILL WOULD:

1. Make a number of findings and declarations about the medical need and use of prefilled self-injection prescription medications.
2. State that the Legislature has found that sharps mail-back programs approved by the U.S. Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that cooperative efforts of the pharmaceutical industry is necessary to develop a safe needle disposal system.
3. Requires that upon request of a consumer who has been dispensed a prefilled syringe, prefilled pen, or other prefilled injection device administered at home, the manufacturer must arrange to provide either of the following:
   - A postage prepaid, mail-back sharps container that has been approved by the U.S. Postal Service and the Department of Public Health (DPH)
   - A sharps container for the safe storage and delivery to a sharps consolidation location approved by the DPH or to a clinic, physician or pharmacy that accepts home-generated sharps waste.
4. Requires that the pharmaceutical manufacturer provide information on safe disposal alternatives and options for sharps as well as a notice to consumers that effective September 1, 2008, California law prohibits a person from disposing of such items in any container used for collection of solid waste, recycle, green waste or commercial collection of solid waste or recyclable materials from business establishments.
5. Defines "sharps container" consistent with the definition in Health and Safety Code Section 117750.

AUTHOR'S INTENT

This bill is intended as a continuation of the legislation regarding the safe needle program - - and to further that purpose. Consumers currently do not have a safe way to dispose of used needles and syringes. According to the author, at least two billion lawful injections of medications occur yearly outside of health care settings in California and that most of these used needles end up in household trash, posing a signification risk or injury and/or infection.

COMMENTS

As initially introduced, this bill would have required a pharmaceutical company whose product is dispensed in the form of a prefilled syringe, prefilled pen, or other prefilled injection device to make available, at no cost and through an annually renewable program, postage pre-paid, mail-back sharps containers. This bill has been amended several times.

PRIOR HISTORY/RELATED BILLS

SB 1305 (Figueroa) Chapter 64, Statutes of 2006 – Prohibits, as of September 1, 2008, a person from placing home-generated sharps waste in specified commercial and residential solid waste collection containers, including containers used for recyclable materials or greenwaste as well as roll-off containers used for construction and demolition debris. It also requires that home-generated sharps waste be transported in an approved sharps container with an approved facility approved by the Department of Toxics and removes home-generated sharps waste as among those items subject to the state's medical waste control laws. The board had no position on this legislation.

FISCAL IMPACT

The board does not anticipate any substantial fiscal impact on its operations. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION

Support
Alameda County Board of Supervisors (Sponsor)
California Association of Environmental Health Administrators (if amended)
California Association of Sanitation Agencies
California Conference of Machinists
California Labor Federation
California Nurses Association
California Refuse Removal Council
County of Santa Clara Board of Supervisors
Engineers and Scientists of California
Los Angeles County Solid Waste Management Committee
National Multiple Sclerosis Society-California Action Network

Planning and Conservation League
Regional Council of Rural Counties (Support if amended)
San Mateo County Central Labor Council
Solid Waste Association of North America
United Food and Commercial Workers Union, Western States Council

Oppose
Amgen
California Healthcare Institute
Del Norte Solid Waste Management Authroity (Oppose unless amended)
Sanofi-aventis

HISTORY:

Date	Action
06/26/08	June 26 From committee: Do pass. (Ayes 6. Noes 3.)
06/19/08	June 19 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
06/11/08	June 11 In committee: Set, first hearing. Hearing canceled at the request of author. From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
05/06/08	May 6 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
03/13/08	Mar. 13 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
02/07/08	Feb. 7 Referred to Com. on HEALTH.
01/30/08	Jan. 30 In Senate. Read first time. To Com. on RLS. for assignment.
01/29/08	Jan. 29 Read third time, amended, and returned to third reading. (Page 3855.). Assembly Rule 69(d) suspended. Read third time, passed, and to Senate. (Ayes 45. Noes 27. Page 3871.)
01/17/08	Jan. 17 Read second time. To third reading.
01/16/08	Jan. 16 From committee: Do pass. (Ayes 9. Noes 6.) (January 15).
01/10/08	Jan. 10 Re-referred to Com. on HEALTH.
01/09/08	Jan. 9 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
01/08/08	Jan. 8 Re-referred to Com. on HEALTH.
01/07/08	Jan. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
06/25/07	June 25 Re-referred to Com. on HEALTH.
06/21/07	June 21 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
05/08/07	May 8 In committee: Set, second hearing. Hearing canceled at the request of author.
05/01/07	May 1 In committee: Set, first hearing. Hearing canceled at the request of author.
05/01/07	May 1 Re-referred to Com. on HEALTH.
04/30/07	Apr. 30 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

03/22/07 Mar. 22 Referred to Com. on HEALTH.

02/21/07 Feb. 21 From printer. May be heard in committee March 23.

02/20/07 Feb. 20 Read first time. To print.

AMENDED IN SENATE JUNE 24, 2008

AMENDED IN ASSEMBLY JANUARY 22, 2008

AMENDED IN ASSEMBLY JANUARY 17, 2008

AMENDED IN ASSEMBLY APRIL 23, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 865

Introduced by Assembly Member Davis

February 22, 2007

An act to amend Section 11022 of the Government Code, relating to state agencies.

LEGISLATIVE COUNSEL'S DIGEST

AB 865, as amended, Davis. State agencies: live customer service agents.

Existing law requires each state agency to establish a procedure whereby incoming telephone calls on any public line shall be answered within 10 rings during regular business hours, subject to certain exceptions.

This bill would name these provisions the State Agency Live Customer Service Act. It would require each state agency to answer an incoming call on its main public line with a live customer service agent or automated telephone answering equipment with an automated prompt that allows a caller to select the option to speak with a live customer service agent, subject to certain exceptions.

Existing law provides for the State and Consumer Services Agency, the Business, Transportation and Housing Agency, the California Environmental Protection Agency, the California Health and Human

Services Agency, the Labor and Workforce Development Agency, the Resources Agency, and the Youth and Adult Correctional Agency in state government.

This bill would specify that its provisions only apply to these designated agencies.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 11022 of the Government Code is amended to read:

11022. (a) This section shall be known and may be cited as the State Agency Live Customer Service Act.

(b) Each state agency shall establish a procedure pursuant to which incoming telephone calls on the main public line shall be answered by a live customer service agent, or automated telephone answering equipment in accordance with subdivision (c), within 10 rings during regular business hours as set forth in Section 11020, except when emergency or illness requires adjustments to normal staffing levels.

(c) During regular business hours, as set forth in Section 11020, the headquarters of every state agency that uses automated telephone answering equipment shall have for all incoming telephone calls on the main public line, an automated prompt that allows a caller to select the option to speak with a live customer service agent and shall have a live customer service agent available for this purpose.

(d) Subdivision (c) does not apply to telephone lines dedicated as hotlines for emergency services, telephone lines dedicated exclusively to providing general information, and any system that is designed to permit an individual to conduct a complete transaction with a state agency over the telephone solely by pressing one or more touch-tone telephone keys in response to automated prompts.

(e) For the purposes of this section, the following definitions shall apply:

(1) "Headquarters" means the chief executive office of the agency designated by the director or head of the agency as its main office.

(2) "Main public line" means the line designated by the director or head of the agency as its main public line.

(f) Notwithstanding Section 11000, for the purposes of this section, "agency" refers only to those agencies listed in Section 12800.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 865 **VERSION: As amended June 24, 2008**

AUTHOR: Davis **SPONSOR: Author**

BOARD POSITION: Neutral

SUBJECT: State agencies, live customer service agents

EXISTING LAW:

Requires each state agency to establish a procedure to ensure that incoming calls on any public line will be answered within 10 rings during regular business hours.

THIS BILL WOULD:

1. Require the headquarter for specified state agencies to answer telephone calls on the main public line by a live customer service agent within 10 rings during regular business hours or an automated answering service. If an automated answering service is used, an option must be available to the caller to speak with a live customer service agent.
2. Exempt telephone lines dedicated as hotlines for emergency services, telephone lines dedicated exclusively to provide general information and others as specified.
3. Define headquarters as the office or agency located in Sacramento, or where the director or head of the agency is located.
4. Defines "main public line" means the line designated by the director or head of the agency as its main public line.
5. Specifies that the requirements only apply to the following agencies:
    - The State and Consumer Services Agency
    - The Business, Transportation and Housing Agency
    - The California Environmental Protection Agency
    - The California Health and Human Services Agency
    - The Labor and Workforce Development Agency
    - The Resources Agency

- The Youth and Adult Correctional Agency

AUTHOR'S INTENT

This legislation is intended address the general frustration some constituents experience trying to access a live agent to speak with. Illinois enacted a similar requirement in 2005.

FISCAL IMPACT

Should this bill be enacted, the board would need to pursue a part-time office assistant to help assist board receptionists during peak calling times, (e.g., Mondays, during renewal cycles etc.).

COMMENTS

As initially introduced, this requirement applied to all state agencies requiring each state agency to answer telephone calls on any public line by a live customer service agent within 10 rings during regular business hours. This legislation has been amended four times. According to the department, based on the recent amendments, the requirements detailed in this legislation would not apply to the board. Staff has requested confirmation from counsel on this determination and will provide an update at the committee meeting.

SUPPORT/OPPOSITION

Support
American Federation of State, County and Municipal Employees
CALPIRG
Consumer Federation of California
Secretary of State Debra Bowen
Service Employees International Union Local 1000

Oppose
Department of Finance

HISTORY

Dates	Actions
06/24/08	June 24 Read second time, amended, and to third reading.
06/23/08	June 23 From committee: Be placed on second reading file pursuant to Senate Rule 28.8 and be amended.
05/13/08	May 13 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 8. Noes 0.) .
02/07/08	Feb. 7 Referred to Com. on G.O.
01/28/08	Jan. 28 In Senate. Read first time. To Com. on RLS. for assignment.
01/28/08	Jan. 28 Read third time, passed, and to Senate. (Ayes 76. Noes 0. Page 3835.)
01/24/08	Jan. 24 From committee: Do pass. (Ayes 16. Noes 0. Page 3814.) (January 24). Read second time. To third reading.
01/23/08	Jan. 23 Re-referred to Com. on APPR.
01/22/08	Jan. 22 From committee chair, with author's amendments: Amend, and re-refer to Com. on APPR. Read second time and amended.
01/18/08	Jan. 18 Re-referred to Com. on APPR.
01/17/08	Jan. 17 Read second time and amended.
01/16/08	Jan. 16 From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (January 15).
04/24/07	Apr. 24 Re-referred to Com. on B. & P.
04/23/07	Apr. 23 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/17/07	Apr. 17 In committee: Set, second hearing. Hearing canceled at the request of author.
04/10/07	Apr. 10 In committee: Set, first hearing. Hearing canceled at the request of author.
03/12/07	Mar. 12 Referred to Com. on B. & P.
02/23/07	Feb. 23 From printer. May be heard in committee March 25.
02/22/07	Feb. 22 Read first time. To print.

AMENDED IN SENATE JUNE 24, 2008

AMENDED IN SENATE JUNE 2, 2008

AMENDED IN ASSEMBLY JANUARY 9, 2008

AMENDED IN ASSEMBLY JANUARY 7, 2008

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1394

Introduced by Assembly Member Krekorian

February 23, 2007

An act to amend Section 350 of the Penal Code, relating to counterfeiting.

LEGISLATIVE COUNSEL'S DIGEST

AB 1394, as amended, Krekorian. Counterfeit: trademarks.

Existing law makes it a misdemeanor or a felony for a person to willfully manufacture, intentionally sell, or knowingly possess for sale any counterfeit registered trademark, as specified. Existing law also provides, upon conviction, for the forfeiture and destruction of all the counterfeit trademarks and related articles, as specified. Existing law regarding counterfeited trademarks also applies to unassembled components of computer software packages. Under existing law, a court is required to order restitution, as specified, to a victim of a crime.

~~This bill would, in addition, make it a misdemeanor or a felony for a person or business entity, as specified, to intentionally transport, offer for sale, or distribute any counterfeit registered trademark, as specified. This bill would also increase the maximum fine allowed to be imposed upon conviction. This bill would require the forfeiture of all proceeds from the willful manufacture, intentional transport, sale, offering for~~

~~sale, distribution, or knowing possession for sale of any counterfeit registered trademark. This bill would also apply provisions related to counterfeited trademarks to unassembled components, as specified, and would require restitution to be paid to the victim of a trademark offense.~~

This bill would remove the requirement that the sale of the counterfeit mark be intentional. This bill would, in addition, make it a misdemeanor or a felony for a business entity, as defined, to willfully manufacture, sell, or knowingly possess for sale any counterfeit registered trademark, as specified. This bill would specify the procedure for the forfeiture of the counterfeited items. This bill would also expand the definition of a "counterfeit mark."

Because this bill would expand the definition of an existing crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 350 of the Penal Code is amended to read:

350. (a) Any person or business entity who willfully manufactures, ~~intentionally transports,~~ sells, ~~offers for sale, or distributes;~~ or knowingly possesses for sale any counterfeit mark registered with the Secretary of State or registered on the Principal Register of the United States Patent and Trademark Office, shall, upon conviction, be punishable as follows:

(1) When the offense involves less than 1,000 of the articles described in this subdivision, with a total retail or fair market value less than that required for grand theft as defined in Section 487, and if the person is an individual, he or she shall be punished by a fine of not more than five thousand dollars ($5,000), or by imprisonment in a county jail for not more than one year, or by both that fine and imprisonment; or, if the person is a business entity, by a fine of not more than one hundred thousand dollars ($100,000).

(2) When the offense involves 1,000 or more of the articles described in this subdivision, or has a total retail or fair market value equal to or greater than that required for grand theft as defined in Section 487, and if the person is an individual, he or she shall be punished by imprisonment in a county jail not to exceed one year, or in the state prison for 16 months, or two or three years, or by a fine not to exceed ~~the greater of~~ two hundred fifty thousand dollars ($250,000), or ~~three times the total retail or fair market value of the articles described in this subdivision, or~~ by both that imprisonment and fine; or, if the offender is a business entity, by a fine not to exceed ~~the greater of~~ five hundred thousand dollars ($500,000) ~~or three times the total retail or fair market value of the articles described in this subdivision.~~.

(b) Any offender who has been convicted of a violation of either paragraph (1) or (2) of subdivision (a) shall, upon a subsequent conviction of paragraph (1) of subdivision (a), if the offender is an individual, be punished by a fine of not more than fifty thousand dollars ($50,000), or by imprisonment in a county jail for not more than one year, or in the state prison for 16 months, or two or three years, or by both that fine and imprisonment; or, if the offender is a business entity, by a fine of not more than two hundred thousand dollars ($200,000).

(c) Any offender who has been convicted of a violation of subdivision (a) and who, by virtue of the conduct that was the basis of the conviction, has directly and foreseeably caused death or great bodily injury to another through reliance on the counterfeited item for its intended purpose shall, if the person is an individual, be punished by a fine of not more than fifty thousand dollars ($50,000), or by imprisonment in the state prison for two, three, or four years, or by both that fine and imprisonment; or, if the offender is a business entity, by a fine of not more than two hundred thousand dollars ($200,000).

(d) In any action brought under this section resulting in a conviction or a plea of nolo contendere, the court shall order the forfeiture and destruction of all of those marks and of all goods, articles, or other matter bearing the marks, and the forfeiture and destruction or other disposition of all means of making the marks, and any and all electrical, mechanical, or other devices for manufacturing, reproducing, transporting, or assembling these marks, that were used in connection with, or were part of, any

violation of this ~~section, and the forfeiture of all proceeds of the crime.~~ *section. Forfeiture of the proceeds of the crime shall be subject to Chapter 9 (commencing with Section 186) of Title 7 of Part 1.* However, no vehicle shall be forfeited under this section that may be lawfully driven on the highway with a class 3 or 4 license, as prescribed in Section 12804 of the Vehicle Code, and that is any of the following:

(1) A community property asset of a person other than the defendant.

(2) The sole class 3 or 4 vehicle available to the immediate family of that person or of the defendant.

(3) Reasonably necessary to be retained by the defendant for the purpose of lawfully earning a living, or for any other reasonable and lawful purpose.

(e) For the purposes of this section, the following definitions shall apply:

(1) When counterfeited but unassembled components of computer software packages are recovered, including, but not limited to, counterfeited computer diskettes, instruction manuals, or licensing envelopes, the number of "articles" shall be equivalent to the number of completed computer software packages that could have been made from those components.

(2) "Business entity" includes, but is not limited to, a corporation~~;~~ *or a* limited liability ~~company, or sole proprietorship.~~ *company. "Business entity" does not include a sole proprietorship.*

(3) "Counterfeit mark" means a spurious mark that is identical with, or confusingly similar to, a registered mark and is used, or intended to be used, on or in connection with the same type of goods or services for which the genuine mark is registered. It is not necessary for the mark to be displayed on the outside of an article for there to be a violation. For articles containing digitally stored information, it shall be sufficient to constitute a violation if the counterfeit mark appears on a video display when the information is retrieved from the article. The term "spurious mark" includes genuine marks used on or in connection with spurious articles and includes identical articles containing identical marks, where the goods or marks were reproduced without authorization of, or in excess of any authorization granted by, the registrant. When counterfeited but unassembled components of any articles described under subdivision (a) are recovered, including, but not

limited to, labels, patches, fabric, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging, or any other components of any type or nature that are designed, marketed, or otherwise intended to be used on or in connection with any articles described under subdivision (a), the number of "articles" shall be equivalent to the number of completed articles that could have been made from those components.

~~(4) "Intentionally transports," "intentionally offers for sale," or "intentionally distributes" requires knowing possession, custody, or control.~~

~~(5)~~

(4) "Knowingly possess" means that the person or business entity possessing an article knew or had reason to believe that it was spurious, or that it was used on or in connection with spurious articles, or that it was reproduced without authorization of, or in excess of any authorization granted by, the registrant.

~~(6)~~

(5) "Registrant" means any person or business entity to whom the registration of a mark is issued and that person's or business entity's legal representatives, successors, or assigns.

~~(7)~~

(6) "Sale" includes resale.

~~(8)~~

(7) "Value" has the following meanings:

(A) When counterfeit items of computer software are manufactured or possessed for sale, the "value" of those items shall be equivalent to the retail price or fair market price of the true items that are counterfeited.

(B) When counterfeited but unassembled components of computer software packages or any other articles described under subdivision (a) are recovered, including, but not limited to, counterfeited digital disks, instruction manuals, licensing envelopes, labels, patches, fabric, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging, or any other components of any type or nature that are designed, marketed, or otherwise intended to be used on or in connection with any articles described under subdivision (a), the "value" of those components shall be equivalent to the retail price or fair market value of the number of

completed computer software packages or other completed articles described under subdivision (a) that could have been made from those components.

(C) "Retail or fair market value" of a counterfeit article means a value equivalent to the retail price or fair market value, as of the last day of the charged crime, of a completed similar genuine article containing a genuine mark.

(f) This section shall not be enforced against any party who has adopted and lawfully used the same or confusingly similar mark in the rendition of like services or the manufacture or sale of like goods in this state from a date prior to the earliest effective date of registration of the service mark or trademark either with the Secretary of State or on the Principle Register of the United States Patent and Trademark Office.

(g) An owner, officer, employee, or agent who provides, rents, leases, licenses, or sells real property upon which a violation of subdivision (a) occurs shall not be subject to a criminal penalty pursuant to this section, unless he or she sells, or possesses for sale, articles bearing a counterfeit mark in violation of this section. This subdivision shall not be construed to abrogate or limit any civil rights or remedies for a trademark violation.

(h) This section shall not be enforced against any party who engages in fair uses of a mark, as specified in Section 14247 of the Business and Professions Code.

(i) When a person or business entity is convicted of an offense under this section, the court shall order the person to pay restitution to the trademark owner and any other victim of the offense pursuant to Section 1202.4.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1394 **VERSION: As amended June 24, 2008**

AUTHOR: Krekorian **SPONSOR: California Chamber of Commerce**

BOARD POSITION: Support

SUBJECT: Counterfeit Trademarks

EXISTING LAW

1. Prohibits the manufacture, sale and possession for sale of counterfeit products as specified in Penal Code §350.
2. Establishes the penalties for an offense and sets fine amounts of $250,000 for individuals and $500,000 for corporations for an offense that involves 1,000 or more articles.
3. Requires as part of a conviction or a plea of nolo contendere, the forfeiture and destruction of all of those marks and of all goods, articles and other matter bearing marks used in connection with, or were part of any violation.
4. Defines counterfeit mark.

THIS BILL WOULD

1. Require as part of a conviction or a plea of nolo contendere, that forfeiture of all proceeds of the crime shall be subject to Chapter 9 (commencing with Section 186) of Title 7 of Part 1.
2. Specifies that a business entity includes a corporation, or limited liability company, and does not include a sole proprietorship.
3. Expand the definition of a counterfeit mark to also include not only those marks used, but also those intended to be used. Clarify that when counterfeited but unassembled components of any articles are recovered, the number of articles shall be equivalent to the number of completed articles that could have been made from those components.

4. Expand the unassembled components of articles to be included when determining the value that could have been made from the components.
5. Require the court to order a convicted person of an offense to pay restitution to the trademark owner or other victim of the offense.
6. Shall not be enforced against any party who engages in fair uses of a mark, as specified in Section 14247 of the Business and Professions Code.

AUTHOR'S INTENT

According to the Sponsor, current law is unclear and lacks consistency with federal law. Several unclear provisions create loopholes that undermine enforcement efforts.

COMMENT

This bill has been amended several times. As amended in January 2008, this proposal would have strengthened the criminal penalties against counterfeit operations and mesh with our public protection mandate and e-pedigree requirements. Several of these provisions were subsequently amended out of the proposal.

FISCAL IMPACT

The board does not anticipate any substantial fiscal impact on its operations. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION

Support
California Alliance for Consumer Protection
California Grocers Association
California Retailers Association
International AntiCounterfeiting Coalition
United States Chamber of Commerce
Valley Industry and Commerce Association

Oppose
None on file

HISTORY

Dates	Actions
06/24/08	June 24 Read second time, amended, and re-referred to Com. on APPR.
06/23/08	June 23 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 4. Noes 0.) .
06/04/08	June 4 In committee: Set, first hearing. Hearing canceled at the request of author.
06/02/08	June 2 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on PUB. S.
05/23/08	May 23 Withdrawn from committee. Re-referred to Com. on PUB. S.
02/07/08	Feb. 7 Referred to Coms. on JUD. and PUB. S.
01/28/08	Jan. 28 In Senate. Read first time. To Com. on RLS. for assignment.
01/28/08	Jan. 28 Read third time, passed, and to Senate. (Ayes 75. Noes 0. Page 3840.)
01/24/08	Jan. 24 In committee: Set, first hearing. Referred to APPR. suspense file. From committee: Do pass. (Ayes 16. Noes 0. Page 3814.) (January 24). Read second time. To third reading.
01/16/08	Jan. 16 From committee: Do pass, and re-refer to Com. on APPR. with recommendation: To Consent Calendar. Re-referred. (Ayes 7. Noes 0.) (January 15).
01/10/08	Jan. 10 Re-referred to Com. on PUB. S.
01/09/08	Jan. 9 From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
01/08/08	Jan. 8 Re-referred to Com. on PUB. S.
01/07/08	Jan. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
03/22/07	Mar. 22 Referred to Com. on PUB. S.
02/26/07	Feb. 26 Read first time.
02/25/07	Feb. 25 From printer. May be heard in committee March 27.
02/23/07	Feb. 23 Introduced. To print.

AMENDED IN SENATE JUNE 10, 2008

AMENDED IN SENATE MAY 23, 2008

AMENDED IN ASSEMBLY JANUARY 7, 2008

AMENDED IN ASSEMBLY MAY 30, 2007

AMENDED IN ASSEMBLY APRIL 17, 2007

AMENDED IN ASSEMBLY APRIL 9, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1436

Introduced by Assembly Member Hernandez
(Coauthor: Assembly Member Niello)

February 23, 2007

An act to amend Sections 2725.5 and 2835.5 of, and to add Section 2835.7 to, the Business and Professions Code, relating to nursing.

LEGISLATIVE COUNSEL'S DIGEST

AB 1436, as amended, Hernandez. Nurse practitioners.

Existing law, the Nursing Practice Act, provides for the certification and regulation of nurse practitioners and nurse-midwives by the Board of Registered Nursing and specifies requirements for qualification or certification as a nurse practitioner. Under the act, the practice of nursing is defined, in part, as providing direct and indirect patient care services, as specified, including dispensing of drugs or devices upon their order in a clinic setting, as defined.

This bill would provide that a nurse practitioner is authorized to perform comprehensive health care services, *as specified,* for which he or she is educationally prepared and competent to perform, and *is*

authorized to admit and discharge patients from health facilities, *change a treatment regimen, or initiate an emergency procedure,* in collaboration, as defined, with specified healing arts practitioners. The bill would ~~deem specified authorizations by a physician and surgeon to include authorizations provided by a certified nurse practitioner~~ *make a nurse practitioner independently responsible for the performance of these services*. The bill would require a certified nurse practitioner to consult or refer a patient to another health care provider if a situation or condition occurs beyond the nurse practitioner's knowledge and experience. The bill also would revise the educational requirements for qualification or certification as a nurse practitioner and would require a nurse practitioner to be certified by a nationally recognized certifying body approved by the board. The bill would require the board to adopt specified regulations.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 2725.5 of the Business and Professions Code is amended to read:

2725.5. (a) "Advanced practice registered nurse" means those licensed registered nurses who have met the requirements of Article 2.5 (commencing with Section 2746), Article 7 (commencing with Section 2825), Article 8 (commencing with Section 2834), or Article 9 (commencing with Section 2838).

(b) Advanced practice registered nursing is based on knowledge and skills acquired in basic nursing education, licensure as a registered nurse, graduation from a graduate level advanced practice registered nursing program approved by the board, and current certification by a national certifying body in the appropriate advanced practice registered nursing role and specialty.

SEC. 2. Section 2835.5 of the Business and Professions Code is amended to read:

2835.5. (a) A registered nurse who is holding himself or herself out as a nurse practitioner or who desires to hold himself or herself out as a nurse practitioner shall, within the time prescribed by the board and prior to his or her next license renewal or the issuance of an initial license, submit educational, experience, and other credentials and information as the board may require for it to

determine that the person qualifies to use the title "nurse practitioner," pursuant to the standards and qualifications established by the board.

(b) Upon finding that a person is qualified to hold himself or herself out as a nurse practitioner, the board shall appropriately indicate on the license issued or renewed, that the person is qualified to use the title "nurse practitioner." The board shall also issue to each qualified person a certificate evidencing that the person is qualified to use the title "nurse practitioner."

(c) A person who has been found to be qualified by the board to use the title "nurse practitioner" prior to the effective date of this section shall not be required to submit any further qualifications or information to the board and shall be deemed to have met the requirements of this section.

(d) An applicant for initial qualification or certification as a nurse practitioner under this article who has not been qualified or certified as a nurse practitioner in California or any other state shall meet the following requirements:

(1) Hold a valid and active registered nursing license issued under this chapter.

(2) Possess a master's degree or doctoral degree in nursing.

(3) Satisfactorily complete a nurse practitioner program approved by the board.

(4) Be certified as a nurse practitioner by a nationally recognized certifying body approved by the board.

SEC. 3. Section 2835.7 is added to the Business and Professions Code, to read:

2835.7. (a) A certificate to practice as a nurse practitioner authorizes the holder to provide comprehensive health care ~~services, including, but not limited to, advanced assessment,~~ *services through psychosocial assessment, physical* diagnosis, and management of health and illness needs for which the nurse practitioner has been educationally prepared and is clinically competent to perform.

(b) Notwithstanding any other provision of law, a nurse practitioner, in collaboration with a physician and surgeon or doctor of osteopathy, may admit patients to and discharge patients from hospitals, skilled nursing facilities, nursing facilities, home health care, hospice facilities, and other inpatient facilities, subject to medical staff privileges. ~~"Collaboration," for the purposes of this~~

~~section, is defined as a relationship between a nurse practitioner and a physician and surgeon that includes both autonomous and cooperative decisionmaking, with the nurse practitioner and the physician and surgeon contributing their respective expertise.~~

~~(c) Notwithstanding any other provision of law, whenever any law or regulation requires a signature, certification, stamp, verification, affidavit, or endorsement by a physician and surgeon, it shall be deemed to include a signature, certification, stamp, verification, affidavit, or endorsement by a nurse practitioner.~~ *In addition, a nurse practitioner may, in collaboration with a physician and surgeon or doctor of osteopathy, change any treatment regimen ordered by a physician and surgeon or doctor of osteopathy, or initiate an emergency procedure. "Collaboration" means, for purposes of this section, consultation with a physician and surgeon or doctor of osteopathy in person, telephonically, or electronically.*

~~(d)~~

(c) A nurse practitioner shall consult or refer a patient to a physician and surgeon or other health care provider if the referral will protect the health and welfare of the patient and a situation or condition occurs in a patient that is beyond the nurse practitioner's knowledge and experience.

(d) A nurse practitioner shall be independently responsible for the performance of services authorized by this section.

(e) Nothing in this article shall be construed to limit, revise, or expand the current scope of practice of a registered nurse, as defined in Section ~~2527~~ *2725*.

(f) The board shall adopt regulations necessary to effectuate the purposes of this chapter relating to nurse practitioners, and has sole authority to interpret the practice of nurse practitioners.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1436 **VERSION: As amended June 10, 2008**

AUTHOR: Hernandez **SPONSOR: CA Association for Nurse Practitioners**

BOARD POSITION: None

SUBJECT: Nurse practitioners: scope of practice.

EXISTING LAW

1. Defines the scope of practice for nurse practitioners.
2. Allows a nurse practitioner to dispense drugs pursuant to a protocol and specifies the conditions under which this can be done.
3. Details the requirements for a certificate evidencing that a person is qualified as a nurse practitioner.
4. Specifies the information required on a written order for a prescriber.

THIS BILL WOULD

1. Specify that advanced practice registered nursing is based on knowledge and skills acquired in basic nursing education, licensure as a registered nurse, graduation from a graduate level advanced practice registered nursing program approved by the Board of Registered Nursing (board) and current certification.
2. Revise the education requirement for an initial qualification or certification as a nurse practitioner to include either a master's degree or a doctoral degree in nursing.
3. Require satisfactory completion of a nurse practitioner program approved by the board.
4. Require that the nurse practitioner be certified by a nationally recognized certifying body approved by the board.
5. Allow a certified nurse practitioner to provide comprehensive health care services through psychosocial assessment, physical diagnosis and management of health and illness needs for which the nurse practitioner has been educationally prepared and is clinically competent to perform.
6. Allow a nurse practitioner, in collaboration with a physician, surgeon or doctor of osteopathy, to admit patients and discharge patients from specified healthcare settings.
7. Allow a nurse practitioner, in collaboration with a physician, surgeon or doctor of osteopathy, to change any treatment regimen ordered or initiate an emergency procedure.

8. Require a nurse practitioner to consult or refer a patient to another health care provider if the referral protects the health and welfare of the patient and it situation or condition in the patient is beyond the nurse practitioner's knowledge and experience
9. Specify that a nurse practitioner is independently responsible for the performance of services authorized by this bill.
10. Require the Board of Registered Nursing to promulgate regulations as necessary.

AUTHOR'S INTENT

According to the sponsor, this bill strengthens requirements for licensure as a nurse practitioner, defines the standards for Advanced Practice Registered Nursing, and defines the scope of practice for nurse practitioners. The sponsor indicates that requiring certification will align California with other states that require similar certification and maintain a high level of quality care delivered by nurse practitioners. In addition, the sponsor states that the bill is necessary to define the scope of practice of nurse practitioners and eliminate confusion among stakeholders.

PRIOR HISTORY/RELATED BILLS

SB 809 (Ashburn) defined the scope of practice of nurse practitioners and authorized nurse practitioners to perform specified acts. This bill was never heard and died in committee.

FISCAL IMPACT

The board does not anticipate any fiscal impact. Any minor impact could be absorbed within existing resources.

COMMENTS

This proposal was significantly amended on several occasions. The board did not take a position on this legislation previously; however, earlier discussions by the board about this legislation included concern about the potential increase in prescription errors by nurse practitioners. The provisions to allow for a nurse practitioner to independently prescribe dangerous drugs and devices was amended out of the bill in April 2007.

SUPPORT/OPPOSITION

Support
California Association of Nurse Practitioners (Sponsor)

American Federation of State, County and Municipal Employees
Association of California Health Care Districts
California Family Health Council, Inc.
California Nurses Association (Support if Amended)
United Nurses Association of California/Union of Health Care Professionals
Numerous individuals, including nurse practitioners

Oppose
American College of Obstetricians and Gynecologists District IX
American Society for Dermatologic Surgery Association
California Academy of Eye Physicians and Surgeons
California Academy of Family Physicians
California Academy of Physician Assistants
California Medical Association
California Society of Health Systems Pharmacists
California Society of Plastic Surgeons
Medical Board of California

HISTORY:

Dates	Actions
06/10/08	June 10 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
06/04/08	June 4 In committee: Set, first hearing. Hearing canceled at the request of author.
05/23/08	May 23 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
02/07/08	Feb. 7 Referred to Com. on B., P. & E.D.
01/30/08	Jan. 30 In Senate. Read first time. To Com. on RLS. for assignment.
01/29/08	Jan. 29 Read third time, passed, and to Senate. (Ayes 76. Noes 0. Page 3883.)
01/24/08	Jan. 24 From committee: Do pass. To Consent Calendar. (January 24). Read second time. To Consent Calendar.
01/15/08	Jan. 15 From committee: Do pass, and re-refer to Com. on APPR. with recommendation: To Consent Calendar. Re-referred. (Ayes 10. Noes 0.) (January 15).
01/08/08	Jan. 8 Re-referred to Com. on B. & P.
01/07/08	Jan. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
05/31/07	May 31 Re-referred to Com. on B. & P.
05/30/07	May 30 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/24/07	Apr. 24 In committee: Set, first hearing. Hearing canceled at the request of author.
04/23/07	Apr. 23 Joint Rule 62(a), file notice waived. (Page 1106.)
04/18/07	Apr. 18 Re-referred to Com. on B. & P.
04/17/07	Apr. 17 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/10/07	Apr. 10 Re-referred to Com. on B. & P.

04/09/07 Apr. 9 Referred to Coms. on B. & P. and HEALTH. From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.

02/26/07 Feb. 26 Read first time.

02/25/07 Feb. 25 From printer. May be heard in committee March 27.

02/23/07 Feb. 23 Introduced. To print.

AMENDED IN SENATE JUNE 16, 2008

AMENDED IN SENATE JULY 5, 2007

AMENDED IN SENATE JUNE 19, 2007

AMENDED IN ASSEMBLY MAY 15, 2007

AMENDED IN ASSEMBLY MAY 3, 2007

AMENDED IN ASSEMBLY APRIL 23, 2007

AMENDED IN ASSEMBLY MARCH 29, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1574

Introduced by Assembly ~~Member Houston~~ *Members Plescia and Jones*
(Coauthor: Assembly Member Villines)
~~(Coauthor: Senator Dutton)~~

February 23, 2007

~~An act to amend Section 11010 of, and to add Section 11025 to, the Business and Professions Code, and to add Sections 1098, 1098.5, and 1102.6c to the Civil Code, relating to real property.~~ *An act to amend Section 4190 of the Business and Professions Code, relating to clinics.*

LEGISLATIVE COUNSEL'S DIGEST

AB 1574, as amended, ~~Houston~~ *Plescia.* ~~Real property: transfer fees.~~ *Surgical clinics: licensure.*

Existing law, with certain exceptions, provides for the licensure and regulation of clinics, including specialty clinics, by the State Department of Public Health. Existing law defines a specialty clinic to include a

surgical clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. The Pharmacy Law, the knowing violation of which is as misdemeanor, provides that a surgical clinic may not operate and is not entitled to the benefits of specified provisions of the Pharmacy Law without a license issued by the California State Board of Pharmacy. Existing law authorizes the board to inspect a clinic at any time.

This bill would, instead, provide that a surgical clinic that is licensed by the State Department of Public Health, accredited as an outpatient setting, or certified as an ambulatory surgical center to participate in the Medicare Program, as specified, is not entitled to the above-described benefits without a license issued by the board. It would also specify board inspection requirements and would require self-assessments by any clinic licensed by the board. Because this bill would impose new requirements under the Pharmacy Law, the knowing violation of which would be a misdemeanor, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

~~Existing law permits various fees to be included in the price of a residential real estate transfer. Existing law requires the disclosure of specified attributes of residential real property prior to the transfer of title, including disclosure of a continuing lien levy of special taxes, as specified.~~

~~Existing law requires any person who intends to offer subdivided lands within California for sale or lease to file with the Department of Real Estate an application for a public report consisting of a notice of intention and a completed questionnaire that includes, among other things, a statement that there is an airport in the vicinity, and that this may affect the use of the property. Existing law makes a violation of these provisions a crime.~~

~~This bill would regulate the imposition of transfer fees, to be defined as a fee payment requirement imposed in any covenant, restriction, or condition contained in any deed, contract, security instrument, or other document affecting the transfer or sale of real property that requires a fee be paid upon transfer of the real property, with specified exceptions.~~

~~The bill would provide that a transfer fee imposed upon residential real property not otherwise excepted may only be received and used by a public entity or a nonprofit organization to fund a project or facility or to provide a service that provides a public benefit, as specified. The bill would require the facility to be located in, or the service provided in, the same region where the real property is located, as defined. The bill would permit a transfer fee to be imposed only for a period of time no greater than 99 years from the time it is first recorded or until an amount of funding specified in the transfer fee covenant, if any, is collected, and would prohibit the total of transfer fees imposed from exceeding 2% of the sale price of the property. The bill would require a person imposing a transfer fee to make a specified recording in connection with the property, and requires an entity receiving funds from the fee to make a recording when the aggregate amount of funding has been satisfied. The bill would require a transferor of residential real property subject to transfer fees to make a specified disclosure regarding those fees.~~

~~The bill would require the application for a public report in connection with subdivided lands to state whether the property offered for sale or lease is subject to a transfer fee, as specified, and if so, would require a description of how the fee will be used, among other things. By changing the definition of a crime, this bill would impose a state-mandated local program. The bill would require a nonprofit organization accepting a transfer fee, on February 1, 2009, and biennially thereafter, to file a specified report with the department and would authorize the Real Estate Commissioner to cause an examination and report to be made if the entity fails to do so.~~

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. This act shall be known, and may be cited, as the California Outpatient Surgery Patient Safety and Improvement Act.

SEC. 2. Section 4190 of the Business and Professions Code is amended to read:

4190. (a) Notwithstanding any provision of this chapter, a surgical clinic, ~~as defined in~~ *licensed pursuant to* paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, *accredited as an outpatient setting by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or certified as an ambulatory surgical center to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.),* may purchase drugs at wholesale for administration or dispensing, under the direction of a physician *and surgeon*, to patients registered for care at the ~~clinic~~ *facility*, as provided in subdivision (b). The ~~clinic~~ *facility* shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) The drug distribution service of a surgical clinic, *outpatient setting, or ambulatory surgical center* shall be limited to the use of drugs for administration to the patients of the surgical clinic, *outpatient setting, or ambulatory surgical center* and to the dispensing of drugs for the control of pain and nausea for patients of the ~~clinic~~ *facility*. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c) No surgical clinic, *outpatient setting, or ambulatory surgical center* shall ~~operate without a license issued by the board nor shall it~~ be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each ~~clinic~~ *facility* location. A ~~clinic~~ *facility* shall notify the board of any change in the ~~clinic's~~ *facility's* address on a form furnished by the board.

(d) Any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

(e) (1) The board shall inspect an outpatient setting or ambulatory surgical center within 120 days of the issuance of a license pursuant to this article, and at least annually thereafter.

(2) The board may inspect a surgical clinic within 120 days of the issuance of a license pursuant to this article, and at least annually thereafter.

(3) Every surgical clinic, outpatient setting, or ambulatory surgical center issued a license pursuant to this article shall complete a self-assessment within 30 days of opening and at least 30 days before each license renewal pursuant to this article. The completed self-assessment form shall be retained at the licensed premises for a period of three years.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

All matter omitted in this version of the bill appears in the bill as introduced|amended in Senate, July 5, 2007 (JR11)

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1574 **VERSION: As Amended June 16, 2008**

AUTHOR: Plescia **SPONSOR: CA Ambulatory Surgery Assoc.**

RECOMMENDED POSITION:

SUBJECT: Surgical centers: licensure

EXISTING LAW

1. Defines a surgical clinic as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours.
2. Provides that no surgical clinic licensed pursuant to Section 1204 of the Health and Safety Code may purchase drugs at wholesale unless licensed by the California State Board of Pharmacy (board).
3. Defines the licensing requirements for the board to issue a clinic license to an ambulatory surgery center.

THIS BILL WOULD

1. Modify the licensing requirements for a board-issued clinic license for a surgical clinic to include:
   - licensure by the Department of Public Health (DPH) under 1204 and 1212.5 of the Health and Safety Code
   - accreditation by an approved agency or
   - certification to participate in the Medicare Program.

   (This board-issued license would allow the clinic to purchase drugs at wholesale for administration or dispensing as well as commingle medications.)
2. Require the board to inspect a board-licensed surgical clinic that is accredited by an agency or certified to participate in the Medicare Program within 120 days of the issuance of the license and at least on an annual basis thereafter.
3. Require a board licensed surgical clinic to complete a self-assessment within 30 days of issuance of the license and at least 30 days before each license renewal.

AUTHOR'S INTENT

According to the author, a recent court ruling, Capen v. Shewry, prohibits the Department of Public Health from issuing state licenses to ambulatory surgical centers, which are partially or wholly owned by physicians. As a result, such surgical centers do not qualify for a clinic license from the board. The board-issued clinic license allows the facility to maintain a commingled drug supply as well as purchase drugs at wholesale. The author argues that without this proposal, individual physicians will be required to maintain a myriad of medication to dispense at the point of care, as opposed to medication being centralized.

PRIOR HISTORY/RELATED BILLS

AB 2308 (Plescia) of 2006 – This bill was vetoed by the governor. The veto message stated, "While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in these facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner."

The board had no position on this bill.

AB 543 (Plescia) of 2007 – This bill was vetoed by the governor. The veto message stated, "I am returning Assembly Bill 543 without my signature. While I support the intent of this legislation, I am unable to sign it as it lacks critical patient safety protections. This bill doesn't establish appropriate time limits for performing surgery under general anesthesia. Further, it inappropriately restricts administrative flexibility and creates state fiscal pressure during ongoing budget challenges. I am directing the Department of Public Health to pursue legislation that establishes licensure standards for these facilities that are consistent with federal requirements and protect the health and safety of patients. For these reasons, I am returning AB 543 without my signature."

The board had a support position on this bill.

AB 2122 (Plescia) of 2008 – This bill died in the assembly appropriations committee. The board had a support position on this bill.

FISCAL IMPACT

The sponsor believes that 400 or more additional locations would qualify under the new criteria for licensure as a drug clinic by the board. The board anticipates the need for a part-time office technician to process new applications, should all eligible facilities choose to pursue licensure with the board. In addition, the board would require an additional inspector to complete initial and annual inspections of those surgical licenses specified.

Board staff anticipates additional revenue from additional businesses seeking licensure. This revenue would offset a significant portion of the impact incurred with the additional staff required to implement the provision.

COMMENTS

Current law allows the board to issue a clinic license only to an entity licensed by H&S Code section 1204. However there is no requirement that a surgical center must be licensed by the DPH to operate. The unintended consequence is that approximately 400–500 ambulatory surgical centers do not qualify for licensure as a clinic by the board, but would under this bill.

There are currently four approved accreditation agencies:

- American Association for Accreditation of Ambulatory Surgery Facilities Inc. (AAAASF)
- Accreditation Association for Ambulatory Health Care (AAAHC)
- Joint Commission of Accreditation of Healthcare Organizations (JCAHO)
- The Institute for Medical Quality (IMQ)

SUPPORT/OPPOSITION

Support

California Ambulatory Surgery Association (sponsor)

Oppose

California Society of Plastic Surgeons (CSPS) is opposed unless amended to this bill.

HISTORY

Date	Action
06/19/08	June 19 Re-referred to Com. on HEALTH.

06/17/08 June 17 Withdrawn from committee. Re-referred to Com. on RLS.

06/16/08 June 16 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on JUD.

07/10/07 July 10 In committee: Set, first hearing. Hearing canceled at the request of author.

07/05/07 July 5 Read second time, amended, and re-referred to Com. on JUD.

07/03/07 July 3 From committee: Amend, do pass as amended, and re-refer to Com. on JUD. (Ayes 7. Noes 3.) .

06/19/07 June 19 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on T. & H.

06/07/07 June 7 Referred to Coms. on T. & H. and JUD.

05/21/07 May 21 In Senate. Read first time. To Com. on RLS. for assignment.

05/21/07 May 21 Read third time, passed, and to Senate. (Ayes 51. Noes 6. Page 1572.)

05/16/07 May 16 Read second time. To third reading.

05/15/07 May 15 Read second time and amended. Ordered returned to second reading.

05/14/07 May 14 From committee: Amend, and do pass as amended. (Ayes 6. Noes 0.) (May 9).

05/07/07 May 7 Re-referred to Com. on H. & C.D.

05/03/07 May 3 Read second time and amended.

05/02/07 May 2 From committee: Amend, do pass as amended, and re-refer to Com. on H. & C.D. (Ayes 10. Noes 0.) (May 1).

04/24/07 Apr. 24 In committee: Hearing postponed by committee.

04/24/07 Apr. 24 Re-referred to Com. on JUD.

04/23/07 Apr. 23 From committee chair, with author's amendments: Amend, and re-refer to Com. on JUD. Read second time and amended.

04/09/07 Apr. 9 Re-referred to Com. on JUD.

03/29/07 Mar. 29 From committee chair, with author's amendments: Amend, and re-refer to Com. on JUD. Read second time and amended.

03/26/07 Mar. 26 Referred to Coms. on JUD. and H. & C.D.

02/26/07 Feb. 26 Read first time.

02/25/07 Feb. 25 From printer. May be heard in committee March 27.

02/23/07 Feb. 23 Introduced. To print.

AMENDED IN SENATE JUNE 23, 2008

AMENDED IN SENATE JUNE 12, 2008

AMENDED IN ASSEMBLY APRIL 21, 2008

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 2756

Introduced by Assembly Member Duvall

February 22, 2008

An act to amend Section 4062 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2756, as amended, Duvall. Pharmacists: furnishing drugs during emergency.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law authorizes a pharmacist to furnish dangerous drugs or devices in reasonable quantities without a prescription during a federal, state, or local emergency to further the health and safety of the public, as specified. Existing law authorizes the board, during a declared federal, state, or local emergency, to waive application of any provisions of the Pharmacy Law or the regulations adopted thereunder if the waiver will aid in the protection of the public health or the provision of patient care.

This bill would define a federal, state, or local emergency for purposes of these provisions, as specified. The bill would also specify that, for purposes of furnishing dangerous drugs or devices during a federal, state, or local emergency, a pharmacist is not required to await a declaration of emergency so long as the declaration is reasonably

anticipated due to the severity of the ~~conditions believed to constitute an~~ emergency *or natural disaster.*

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4062 of the Business and Professions Code is amended to read:

4062. (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to this chapter if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) For the purposes of subdivision (a), "federal, state, or local emergency" shall mean and include those conditions or degrees of emergency identified in Section 8558 of the Government Code and those forms of disaster identified in Section 8680.3 of the Government Code. For the purposes of subdivision (a), a pharmacist is not required to await a declaration of emergency by federal, state, or local authorities as a prerequisite to acting in good faith to furnish dangerous drugs or dangerous devices in reasonable quantities without a prescription during such emergency, so long as such a declaration is reasonably anticipated due to the severity of the ~~conditions believed to constitute an~~ emergency or *natural* disaster.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2756 **VERSION: As amended June 23, 2008**

AUTHOR: Duvall **SPONSOR: California Retailers Association**

BOARD POSITION: Support

SUBJECT: Pharmacists: furnishing drugs during an emergency

EXISTING LAW

Authorizes a pharmacist to, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state or local emergency, to further the health and safety of the public.

THIS BILL WOULD

Clarify the emergency conditions under which pharmacists may furnish dangerous drugs and devices without a prescription.

AUTHOR'S INTENT

This bill clarifies that a natural disaster is an appropriate emergency in which pharmacists are able to dispense drugs or devices without a prescription to ensure that a delay in a declaration of a state of emergency will not interfere with the ability of patients to receive necessary medications in accordance with board regulations.

FISCAL IMPACT:

The board does not anticipate any substantial fiscal impact to its operations.

SUPPORT/OPPOSITION

Support
California Retailers Association (sponsor)
California Pharmacists Association
National Association of Chain Drug Stores
Walgreens

Oppose
None on file

HISTORY:

Dates	Actions
06/23/08	June 23 Read second time, amended, and to third reading.
06/19/08	June 19 From committee: Amend, and do pass as amended. (Ayes 9. Noes 0.) .
06/12/08	June 12 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
05/29/08	May 29 Referred to Com. on B., P. & E.D.
05/22/08	May 22 In Senate. Read first time. To Com. on RLS. for assignment.
05/22/08	May 22 Read third time, passed, and to Senate. (Ayes 76. Noes 0. Page 5273.)
05/19/08	May 19 Read second time. To Consent Calendar.
05/15/08	May 15 From committee: Do pass. To Consent Calendar. (May 14).
04/29/08	Apr. 29 From committee: Do pass, and re-refer to Com. on APPR. with recommendation: To Consent Calendar. Re-referred. (Ayes 10. Noes 0.) (April 29).
04/22/08	Apr. 22 Re-referred to Com. on B. & P.
04/21/08	Apr. 21 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/03/08	Apr. 3 Referred to Com. on B. & P.
02/25/08	Feb. 25 Read first time.
02/24/08	Feb. 24 From printer. May be heard in committee March 25.
02/22/08	Feb. 22 Introduced. To print.

AMENDED IN ASSEMBLY JULY 1, 2008

AMENDED IN ASSEMBLY JUNE 25, 2007

AMENDED IN SENATE APRIL 16, 2007

SENATE BILL **No. 963**

Introduced by Senator Ridley-Thomas

February 23, 2007

~~An act to amend Sections 22, 102.3, 107, 108, 312, 313.1, 321, 1601.1, 1632.5, 1634.2, 1638.1, 1638.7, 1742, 1751, 2001, 2460, 2531, 2570.19, 2602, 2701, 2841, 2920, 3010.5, 3502.1, 3504, 3685, 3710, 4001, 4003, 4200.1, 4200.3, 4501, 4800, 4928, 4990, 5000, 5510, 5621, 5810, 5811, 6510, 6511, 6710, 7000.5, 7200, 7303, 7810, 8000, 8520, 8710, 9882, 18602, 18602.5, 18824, and 18882 of, to add Sections 27.5, 36, 37, 38, 101.5, 117, 117.5, 127.5, 156.7, and 450.1 to, to add Chapter 4.5 (commencing with Section 360) to Division 1 of, to add Division 1.3 (commencing with Section 474.20) to, to repeal Sections 2569, 4989, 4990.24, 7304, and 22259 of, to repeal Division 1.2 (commencing with Section 473) of, and to repeal and add Section 101.1 of, the Business and Professions Code, and to amend Sections 9148.8 and 9148.51 of, and to repeal Section 9148.52 of, the Government Code, relating to regulatory entities, and making an appropriation therefor.~~ *An act to amend Sections 22, 107, 108, 473.1, 473.2, 473.3, 473.4, and 473.5 of, to add Sections 27.5, 36, 37, 38, 127.5, 473.12, and 473.7 to, and to repeal and add Section 101.1 of, the Business and Professions Code, relating to regulatory boards.*

LEGISLATIVE COUNSEL'S DIGEST

SB 963, as amended, Ridley-Thomas. Regulatory boards: operations.

Existing law creates various regulatory boards, as defined, within the Department of Consumer Affairs ~~and makes their funds separate accounts within the Professions and Vocations Fund. Under existing law, the revenue in certain of these accounts is continuously appropriated to the board, other than fine and penalty revenues~~, *with board members serving specified terms of office. Existing law authorizes each board to appoint a person, exempt from Civil Service, who shall be designated as an executive officer.*

Existing law generally makes the regulatory boards inoperative *and repealed* on ~~a~~ specified ~~date~~ *dates*, unless ~~that date is~~ *those dates are* deleted or extended by subsequent legislation, and subjects these boards *that are scheduled to become inoperative and repealed* as well as other boards in state government, as specified, to review by the Joint Committee on Boards, Commissions, and Consumer Protection. Under existing law, that committee, following a specified procedure, recommends whether the board should be continued or its functions modified.

~~This bill would delete those provisions making the boards inoperative on a specified date and subjecting boards to review by the Joint Committee on Boards, Commissions, and Consumer Protection. The bill would instead make each of those boards subject to review by a standing policy committee of the Legislature upon request by a Member of the Legislature or the chief of the Office of the Consumer Advocate, which the bill would create in the Department of Consumer Affairs. The bill would, upon the committee's determination that a board is deficient, as specified, provide for the removal of all incumbent board members without a hearing and the appointment of a successor board, as specified. The bill would require the Office of the Consumer Advocate to serve as an independent monitor for a board that is found deficient. The bill would authorize the office to appear at meetings and to participate in disciplinary proceedings by a board within the department if required to promote or protect the interests of consumers, as defined, and would require the office to perform other specified duties. The bill would require the office to charge each board a fee to support the office's functions and would thereby make an appropriation by expanding the expenditure purposes of a continuously appropriated fund. The bill would create the Consumer Advocate Fund where these fees would be deposited and would be available to the office upon appropriation by the Legislature. The bill would require the director to~~

~~report annually to the Governor and the Legislature, as specified, on the office's operations.~~

~~The bill would require boards within the department to enter into an agreement with the department for the performance of administrative and ministerial functions and would require the Director of Consumer Affairs, prior to January 1, 2010, to replace the existing technology system serving the department and its component boards and to charge each board its pro rata share of the cost to replace the system.~~

This bill would, notwithstanding any other provision of law, terminate the term of office of each board member of certain boards within the department on specified and unspecified dates. The bill would subject boards that are scheduled to have their board membership so reconstituted to review by the Joint Committee on Boards, Commissions, and Consumer Protection. The bill would also require the appropriate standing policy committee of the Legislature to investigate board deficiencies and to hold specified public hearings.

The bill would also require each board within the department to ~~adopt performance measures, as specified, and report quarterly to the director and the chief of the Office of Consumer Advocate relating to those measures. The bill would also require boards to post the information on their Internet Web site and to report the information to the Legislative Analyst's Office, the Legislature, and the Department of Finance. The bill would require the Office of the Consumer Advocate to report to the Legislature if a board failed to meet its performance measures. The bill would also require those boards to~~ post annually on ~~their~~ *its* Internet Web ~~sites~~ *Site* the number of reports in specified categories that it received that year for its licensees.

The bill would allow a person to serve as the ~~public member of more than one of these boards and would require all members of these boards, as well as bureau chiefs, to report annually to their appointing authority on their goals and objectives and success in achieving them, which would be posted on the board's Internet Web site~~ *executive officer or registrar of more than one board and would make all appointments of an executive officer or registrar subject to approval by the Director of Consumer Affairs and confirmation by the Senate.* The bill would require the department to report to the Legislature and Governor if a board was unable to meet because of a lack of a quorum or vacancy. The bill would require members of these boards and other state boards to report ex parte communications, as defined, in the board's minutes *and would require the department to develop a common method of making boards'*

minutes available to the public. The bill would ~~require~~ *authorize* boards within the department, the State Bar, the Office of Real Estate Appraisers, and other state boards that license professions or businesses to adopt regulations to provide incentives to licensees to provide services on a pro bono basis and to adopt regulations prior to June 30, 2009, establishing regulatory board staffing requirements.

Vote: majority. Appropriation: ~~yes~~ *no*. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 22 of the Business and Professions Code is amended to read:

22. "Board," as used in any provision of this code, refers to the board in which the administration of the provision is vested, and unless otherwise expressly provided, shall include "bureau," "commission," "committee," "department," "division," "examining committee," "program," and "agency."

SEC. 2. Section 27.5 is added to the Business and Professions Code, to read:

27.5. A board within the department shall annually post on its Internet Web site the number of reports it received that year for its licensees in each of the following categories:

(a) Criminal convictions.

(b) Judgments, settlements, or arbitration awards.

(c) Claims paid by a professional liability insurer caused by the licensee's negligence, error, or omission.

SEC. 3. Section 36 is added to the Business and Professions Code, to read:

36. A board within the department, the State Bar, the Office of Real Estate Appraisers, and any other state board that issues a license, certificate, or registration authorizing a person to engage in a business or profession may adopt regulations that provide an incentive to the holder to provide services within the scope of his or her license, certificate, or registration on a pro bono basis. The regulations may reduce the amount of the renewal fee for a licensee, certificate holder, or registrant who demonstrates compliance with the pro bono requirements set forth in the regulations.

SEC. 4. Section 37 is added to the Business and Professions Code, to read:

37. A board within the department and any other state board that issues a license, certificate, or registration authorizing a person to engage in a business or profession ~~shall~~ *may* adopt regulations prior to June 30, 2009, that establish requirements for the number of staff required to adequately investigate and, if appropriate, bring a disciplinary action against a licensee, certificate holder, or registrant regulated by the board. The staff level requirements shall, at a minimum, be the number of staff required per 1,000 persons regulated by the board and include the appropriate number of staff to complete all investigatory and disciplinary functions.

SEC. 5. Section 38 is added to the Business and Professions Code, to read:

38. A member of a board within the department and a member of a state board, as defined in Section 9148.2 of the Government Code, shall disclose all of his or her ex parte communications at the board's next public meeting, and the ex parte communications shall be recorded in the board's minutes. "Ex parte communication" means any oral or written communication concerning matters, other than purely procedural matters, under the board's jurisdiction that are subject to a vote by the board that occurred between the member and a person, other than another board member or an employee of the board or the department of which the board is a part, who intends to influence the decision of the member.

SEC. 6. Section 101.1 of the Business and Professions Code is repealed.

SEC. 7. Section 101.1 is added to the Business and Professions Code, to read:

~~101.1. (a) It is the intent of the Legislature that all existing and proposed consumer-related boards or categories of licensed professionals be subject to ongoing and continuous review as well as a periodic thorough review when issues arise requiring that level of review and such a review is requested by a Member of the Legislature or the chief of the Office of the Consumer Advocate as provided in Division 1.3 (commencing with Section 474.20). The review of a board shall evaluate and determine whether its operations are effectively protecting the public and that protection of the public is the highest priority of the board.~~

~~(b) Notwithstanding any other provision of law, if a board is deemed deficient and its members removed, as described in Section 474.21~~

101.1. Notwithstanding any other provision of law, if the terms of office of the members of a board are terminated in accordance with the act that added this section or by subsequent acts, a successor board shall be appointed that shall succeed to, and be vested with, all the duties, powers, purposes, responsibilities, and jurisdiction not otherwise repealed or made inoperative of the board that it is succeeding. The successor board shall have the same number of members and composition as the board that it is succeeding, and those members shall be appointed by the same appointing authorities, for the same term, and with the same membership requirements as the members of the board it is succeeding. ~~The successor board shall have the same authority to appoint an executive officer as the board that it is succeeding as of the date that board was found deficient. The successor board members shall be appointed within 10 business days of receipt by the Joint Committee on Rules of the deficiency report, as described in Section 474.21.~~

~~SEC. 8. Section 101.5 is added to the Business and Professions Code, to read:~~

~~101.5. (a) Each board within the department shall enter into an agreement with the department for the department to provide administrative and ministerial functions and services, including, but not limited to, personnel services, information technology, the administration of call centers, and the administration of examinations. The Legislature intends that these agreements shall achieve cost savings resulting from economies of scale and a more consistent delivery of services to California consumers and licensees.~~

~~(b) A board shall not enter into an agreement described in subdivision (a) if it would reduce the board's ability to comply with its duties prescribed by law.~~

~~SEC. 9. Section 102.3 of the Business and Professions Code is amended to read:~~

~~102.3. (a) The director may enter into an interagency agreement with an appropriate entity within the Department of Consumer Affairs as provided for in Section 101 to delegate the duties, powers, purposes, responsibilities, and jurisdiction that~~

~~have been succeeded and vested with the department, of a board that became inoperative and was repealed in accordance with Chapter 908 of the Statutes of 1994.~~

~~(b) (1) If, pursuant to subdivision (a), an interagency agreement is entered into between the director and that entity, the entity receiving the delegation of authority may establish a technical committee to regulate, as directed by the entity, the profession subject to the authority that has been delegated. The entity may delegate to the technical committee only those powers that it received pursuant to the interagency agreement with the director. The technical committee shall have only those powers that have been delegated to it by the entity.~~

~~(2) If the entity delegates its authority to adopt, amend, or repeal regulations to the technical committee, all regulations adopted, amended, or repealed by the technical committee shall be subject to the review and approval of the entity.~~

~~(3) The entity shall not delegate to a technical committee its authority to discipline a licentiate who has violated the provisions of the applicable chapter of the Business and Professions Code that is subject to the director's delegation of authority to the entity.~~

~~(c) An interagency agreement entered into, pursuant to subdivision (a), shall continue until the licensing program administered by the technical committee has undergone a review by the Office of the Consumer Advocate to evaluate and determine whether the highest priority of the licensing program is the protection of the public. Thereafter, at the discretion of the chief of that office, the interagency agreement may be renewed.~~

~~SEC. 10.~~

SEC. 8. Section 107 of the Business and Professions Code is amended to read:

107. (a) Pursuant to subdivision (e) of Section 4 of Article VII of the California Constitution, each board may appoint a person exempt from civil service and may fix his or her salary, with the approval of the Department of Personnel Administration pursuant to Section 19825 of the Government Code, who shall be designated as an executive officer unless the licensing act of the particular board designates the person as a registrar. A person may be appointed as an executive officer or registrar for more than one board if approved by each of those boards and may serve in those

capacities at the same time if practical and consistent with law and the respective board functions and duties.

(b) Notwithstanding any other provision of law, all appointments of an executive officer or registrar shall be subject to the approval of the director and confirmation by the Senate.

~~SEC. 11.~~

SEC. 9. Section 108 of the Business and Professions Code is amended to read:

108. (a) Each of the boards comprising the department exists as a separate unit, and has the functions of setting standards, holding meetings, and setting dates thereof, preparing and conducting examinations, passing upon applicants, conducting investigations of violations of laws under its jurisdiction, issuing citations and holding hearings for the revocation of licenses, and the imposing of penalties following those hearings, insofar as these powers are given by statute to each respective board.

(b) The department shall develop a common method of maintaining, posting, and making available to the public minutes of the meetings of the boards comprising the department. Each of those boards shall use that method and shall post the minutes of its meetings on its Internet Web site within 10 days of the date of the meeting.

~~SEC. 12. Section 117 is added to the Business and Professions Code, to read:~~

~~117. (a) Each board within the department shall adopt meaningful, measurable, and manageable performance measures. Performance measures include, but are not limited to, the following information:~~

~~(1) A comprehensive statement of the board's mission, goals, objectives, and legal jurisdiction in protecting the health, safety, and welfare of the public.~~

~~(2) The board's enforcement priorities, complaint and enforcement data, budget expenditures with average and median costs per case, and case aging data specific to post and preaccusation cases at the Attorney General's office.~~

~~(3) The board's fund conditions, sources of revenues, and expenditure categories for the last four fiscal years by program component.~~

~~(4) The board's description of its licensing process including the time and costs required to implement and administer its~~

~~licensing examination, ownership of the license examination, relevancy and validity of the licensing examination, and passage rate and areas of examination.~~

~~(5) The board's initiation of legislative efforts, budget change proposals, and other initiatives it has taken to improve its legislative mandate.~~

~~(b) Each board within the department shall report to the director and the chief of the Office of the Consumer Advocate its performance measures and data relating to those measures on a quarterly basis. Each board shall post quarterly on its Internet Web site the information it reported pursuant to this subdivision and provide the information annually to the Department of Finance, the Legislative Analyst's Office, and the Legislature.~~

~~(c) The chief of the Office of the Consumer Advocate, in consultation with the Legislative Analyst's Office, shall annually review the information reported by boards pursuant to subdivision (b) and report to the Legislature if it determines that a board has failed to meet its performance measures.~~

~~(d) The department may adopt regulations pertaining to the requirements described in subdivision (a).~~

~~SEC. 13. Section 117.5 is added to the Business and Professions Code, to read:~~

~~117.5. (a) Each member of a board within the department and the chief of any bureau within the board shall annually report, on or before December 31 of each year, to the authority that appointed him or her the extent to which the member or chief achieved his or her goals and objectives that year and shall also report the goals and objectives he or she expects to achieve during the following calendar year.~~

~~(b) The board or bureau shall post the reports described in subdivision (a) submitted by its members chief on its Internet Web site within 30 days of their submission date.~~

~~SEC. 14.~~

SEC. 10. Section 127.5 is added to the Business and Professions Code, to read:

127.5. The department shall report to the Legislature and the Governor when a board within the department has been unable to schedule or convene a meeting of the board because of a lack of a quorum caused by the absence of its members or by a vacancy in its membership.

~~SEC. 15. Section 156.7 is added to the Business and Professions Code, to read:~~

~~156.7. (a) Prior to January 1, 2010, the director, in consultation with the State Chief Information Officer, shall replace the department's existing information technology system with a system that meets the requirements of the department and of the boards within the department.~~

~~(b) The director shall charge each of the boards on a pro rata share basis for the costs of replacing the information technology system. The charge shall be an administrative expense that may be levied in advance against the funds of any of the boards pursuant to Section 201.~~

~~(c) Notwithstanding any other provision of this section, the procurement of the information technology system shall be made in accordance with Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code.~~

SEC. 11. Section 473.1 of the Business and Professions Code is amended to read:

473.1. This chapter shall apply to all of the following:

(a) Every board, as defined in Section 22, that is scheduled to ~~become inoperative and to be repealed~~ *have its membership reconstituted* on a specified date as provided by ~~the specific act relating to the board~~ *Section 473.12*.

(b) The Bureau for Postsecondary and Vocational Education. For purposes of this chapter, "board" includes the bureau.

(c) The Cemetery and Funeral Bureau.

SEC. 12. Section 473.12 is added to the Business and Professions Code, to read:

473.12. Notwithstanding any other provision of law, the term of office of each member of the following boards in the department shall terminate on the date listed:

(a) The Dental Board of California: January 1, 2012.

(b) The Medical Board of California: January 1, 2011.

(c) The State Board of Optometry: January 1, 2011.

(d) The California State Board of Pharmacy: January 1, 2011.

(e) The Veterinary Medical Board: January 1, 2012.

(f) The California Board of Accountancy: January 1, 2012.

(g) The California Architects Board: January 1, 2012.

(h) The State Board of Barbering and Cosmetology: January 1, 2012.

(i) The Board for Professional Engineers and Land Surveyors: January 1, 2012.

(j) The Contractors' State License Board: January 1, 2010.

(k) The Bureau for Private Postsecondary Education: ___.

(l) The Structural Pest Control Board: January 1, 2012.

(m) The Bureau of Home Furnishings and Thermal Insulation: ___.

(n) The Board of Registered Nursing: January 1, 2011.

(o) The Board of Behavioral Sciences: January 1, 2010.

(p) The State Athletic Commission: January 1, 2010.

(q) The Cemetery and Funeral Bureau: ___.

(r) The State Board of Guide Dogs for the Blind: January 1, 2012.

(s) The Bureau of Security and Investigative Services: ___.

(t) The Court Reporters Board of California: January 1, 2010.

(u) The Board of Vocational Nursing and Psychiatric Technicians: January 1, 2012.

(v) The Landscape Architects Technical Committee: January 1, 2012.

(w) The Bureau of Electronic and Appliance Repair: ___.

(x) The Division of Investigation, Department of Consumer Affairs: ___.

(y) The Bureau of Automotive Repair: ___.

(z) The Board for Geologists and Geophysicists: January 1, 2010.

(aa) The Respiratory Care Board of California: January 1, 2011.

(ab) The Acupuncture Board: January 1, 2010.

(ac) The Board of Psychology: January 1, 2010.

(ad) The California Board of Podiatric Medicine: January 1, 2011.

(ae) The Physical Therapy Board of California: January 1, 2014.

(af) The Arbitration Review Program: ___.

(ag) The Dental Hygiene Committee of California: ___.

(ah) The Hearing Aid Dispensers Bureau: ___.

(ai) The Physician Assistant Committee, Medical Board of California: January 1, 2012.

(aj) The Speech-Language Pathology and Audiology Board: January 1, 2012.

(ak) The California Board of Occupational Therapy: January 1, 2014.

(al) The Osteopathic Medical Board of California: ___.

(am) The Bureau of Naturopathic Medicine: ___.

SEC. 13. Section 473.2 of the Business and Professions Code is amended to read:

473.2. All boards to which this chapter applies shall, with the assistance of the Department of Consumer Affairs, prepare an analysis and submit a report to the Joint Committee on Boards, Commissions, and Consumer Protection no later than 22 months before that ~~board shall become inoperative~~ *board's membership shall be reconstituted pursuant to Section 473.12.* The analysis and report shall include, at a minimum, all of the following:

(a) A comprehensive statement of the board's mission, goals, objectives and legal jurisdiction in protecting the health, safety, and welfare of the public.

(b) The board's enforcement priorities, complaint and enforcement data, budget expenditures with average- and median-costs per case, and case aging data specific to post and preaccusation cases at the Attorney General's office.

(c) The board's fund conditions, sources of revenues, and expenditure categories for the last four fiscal years by program component.

(d) The board's description of its licensing process including the time and costs required to implement and administer its licensing examination, ownership of the license examination, relevancy and validity of the licensing examination, and passage rate and areas of examination.

(e) The board's initiation of legislative efforts, budget change proposals, and other initiatives it has taken to improve its legislative mandate.

SEC. 14. Section 473.3 of the Business and Professions Code is amended to read:

473.3. (a) Prior to the ~~termination, continuation, or reestablishment of any board or any of the board's functions~~ *reconstitution of the membership of any board described in Section 473.12*, the Joint Committee on Boards, Commissions, and Consumer Protection shall, during the interim recess preceding the date upon which a ~~board becomes inoperative~~ *board's membership is to be reconstituted*, hold public hearings to receive

testimony from the Director of Consumer Affairs, the board involved, and the public and regulated industry. In that hearing, each board shall have the burden of demonstrating a compelling public need for the continued existence of the ~~board or~~ regulatory program, and that its licensing function is the least restrictive regulation consistent with the public health, safety, and welfare.

(b) In addition to subdivision (a), in 2002 and every four years thereafter, the committee, in cooperation with the California Postsecondary Education Commission, shall hold a public hearing to receive testimony from the Director of Consumer Affairs, the Bureau for Private Postsecondary and Vocational Education, private postsecondary educational institutions regulated by the bureau, and students of those institutions. In those hearings, the bureau shall have the burden of demonstrating a compelling public need for the continued existence of the bureau and its regulatory program, and that its function is the least restrictive regulation consistent with the public health, safety, and welfare.

(c) The committee, in cooperation with the California Postsecondary Education Commission, shall evaluate and review the effectiveness and efficiency of the Bureau for Private Postsecondary and Vocational Education, based on factors and minimum standards of performance that are specified in Section 473.4. The committee shall report its findings and recommendations as specified in Section 473.5. The bureau shall prepare an analysis and submit a report to the committee as specified in Section 473.2.

(d) In addition to subdivision (a), in 2003 and every four years thereafter, the committee shall hold a public hearing to receive testimony from the Director of Consumer Affairs and the Bureau of Automotive Repair. In those hearings, the bureau shall have the burden of demonstrating a compelling public need for the continued existence of the bureau and its regulatory program, and that its function is the least restrictive regulation consistent with the public health, safety, and welfare.

(e) The committee shall evaluate and review the effectiveness and efficiency of the Bureau of Automotive Repair based on factors and minimum standards of performance that are specified in Section 473.4. The committee shall report its findings and recommendations as specified in Section 473.5. The bureau shall

prepare an analysis and submit a report to the committee as specified in Section 473.2.

SEC. 15. Section 473.4 of the Business and Professions Code is amended to read:

473.4. (a) The Joint Committee on Boards, Commissions, and Consumer Protection shall evaluate and determine whether a board or regulatory program has demonstrated a public need for the continued existence of the ~~board or~~ regulatory program and for the degree of regulation the board or regulatory program implements based on the following factors and minimum standards of performance:

(1) Whether regulation by the board is necessary to protect the public health, safety, and welfare.

(2) Whether the basis or facts that necessitated the initial licensing or regulation of a practice or profession have changed.

(3) Whether other conditions have arisen that would warrant increased, decreased, or the same degree of regulation.

(4) If regulation of the profession or practice is necessary, whether existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms, and whether the board rules enhance the public interest and are within the scope of legislative intent.

(5) Whether the board operates and enforces its regulatory responsibilities in the public interest and whether its regulatory mission is impeded or enhanced by existing statutes, regulations, policies, practices, or any other circumstances, including budgetary, resource, and personnel matters.

(6) Whether an analysis of board operations indicates that the board performs its statutory duties efficiently and effectively.

(7) Whether the composition of the board adequately represents the public interest and whether the board encourages public participation in its decisions rather than participation only by the industry and individuals it regulates.

(8) Whether the board and its laws or regulations stimulate or restrict competition, and the extent of the economic impact the board's regulatory practices have on the state's business and technological growth.

(9) Whether complaint, investigation, powers to intervene, and disciplinary procedures adequately protect the public and whether

final dispositions of complaints, investigations, restraining orders, and disciplinary actions are in the public interest; or if it is, instead, self-serving to the profession, industry or individuals being regulated by the board.

(10) Whether the scope of practice of the regulated profession or occupation contributes to the highest utilization of personnel and whether entry requirements encourage affirmative action.

(11) Whether administrative and statutory changes are necessary to improve board operations to enhance the public interest.

(b) The Joint Committee on Boards, Commissions, and Consumer Protection shall consider alternatives to placing responsibilities and jurisdiction of the board under the Department of Consumer Affairs.

(c) Nothing in this section precludes any board from submitting other appropriate information to the Joint Committee on Boards, Commissions, and Consumer Protection.

SEC. 16. Section 473.5 of the Business and Professions Code is amended to read:

473.5. The Joint Committee on Boards, Commissions, and Consumer Protection shall report its findings and preliminary recommendations to the department for its review, and, within 90 days of receiving the report, the department shall report its findings and recommendations to the Joint Committee on Boards, Commissions, and Consumer Protection during the next year of the regular session that follows the hearings described in Section 473.3. The committee shall then meet to vote on final recommendations. A final report shall be completed by the committee and made available to the public and the Legislature. The report shall include final recommendations of the department and the committee and whether ~~each board or function scheduled for repeal shall be terminated, continued, or reestablished,~~ *the board's membership should be reconstituted* and whether its functions should be revised. If the committee or the department deems it advisable, the report may include proposed bills to carry out its recommendations.

SEC. 17. Section 473.7 is added to the Business and Professions Code, to read:

473.7. The appropriate standing policy committee of the Legislature shall, through its oversight function, investigate the perceived deficiencies in the operation of a board to which this

chapter applies and hold public hearings on any matter subject to public hearing under Section 473.3.

~~SEC. 16. Section 312 of the Business and Professions Code is amended to read:~~

~~312. (a) The director shall submit to the Governor and the Legislature on or before January 1, 2003, and annually thereafter, a report of programmatic and statistical information regarding the activities of the department and its constituent entities. The report shall include information concerning the director's activities pursuant to Section 326, including the number and general patterns of consumer complaints and the action taken on those complaints.~~

~~(b) On or before January 1 of each year, beginning in 2009, the director shall submit to the chairperson of the fiscal committee of each house of the Legislature and to the Joint Legislative Budget Committee all of the following information:~~

~~(1) The number of personnel years assigned to the Office of the Consumer Advocate.~~

~~(2) The total dollars expended by the Office of the Consumer Advocate in the prior year, the estimated total dollars expended in the current year, and the total dollars proposed for appropriation in the following budget year.~~

~~(3) Workload standards and measures for the Office of the Consumer Advocate.~~

~~SEC. 17. Section 313.1 of the Business and Professions Code is amended to read:~~

~~313.1. (a) Notwithstanding any other provision of law to the contrary, no rule or regulation, except those relating to examinations and qualifications for licensure, and no fee change proposed or promulgated by any of the boards, commissions, or committees within the department, shall take effect pending compliance with this section.~~

~~(b) The director and the chief of the Office of the Consumer Advocate shall be formally notified of and shall be provided a full opportunity to review, in accordance with the requirements of Article 5 (commencing with Section 11346) of Chapter 3.5 of Part 1 of Division 3 of Title 2 of the Government Code, and this section, all of the following:~~

~~(1) All notices of proposed action, any modifications and supplements thereto, and the text of proposed regulations.~~

~~(2) Any notices of sufficiently related changes to regulations previously noticed to the public, and the text of proposed regulations showing modifications to the text.~~

~~(3) Final rulemaking records.~~

~~(c) The submission of all notices and final rulemaking records to the director and the chief of the Office of the Consumer Advocate and the completion of their review, as authorized by this section, shall be a precondition to the filing of any rule or regulation with the Office of Administrative Law. The Office of Administrative Law shall have no jurisdiction to review a rule or regulation subject to this section until after the completion of the director's review and only then if the director and the chief of the Office of the Consumer Advocate have not disapproved it. The filing of any document with the Office of Administrative Law shall be accompanied by a certification that the board, commission, or committee has complied with the requirements of this section.~~

~~(d) Following the receipt of any final rulemaking record subject to subdivision (a), the director and the chief of the Consumer Advocate shall have the authority for a period of 30 days to disapprove a proposed rule or regulation on the ground that it is injurious to the public health, safety, or welfare.~~

~~(e) Final rulemaking records shall be filed with the director and the chief of the Office of the Consumer Advocate within the one-year notice period specified in Section 11346.4 of the Government Code. If necessary for compliance with this section, the one-year notice period may be extended, as specified by this subdivision.~~

~~(1) If the one-year notice period lapses during the 30-day review period, or within 60 days following the notice of disapproval, it may be extended for a maximum of 90 days.~~

~~(2) If the director and the chief approve the final rulemaking record or declines to take action on it within 30 days, the board, commission, or committee shall have five days from the receipt of the record from the director and the chief within which to file it with the Office of Administrative Law.~~

~~(3) If the director or the chief disapproves a rule or regulation, it shall have no force or effect unless, within 60 days of the notice of disapproval, (A) the disapproval is overridden by a unanimous vote of the members of the board, commission, or committee, and (B) the board, commission, or committee files the final rulemaking~~

record with the Office of Administrative Law in compliance with this section and the procedures required by Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(f) Nothing in this section shall be construed to prohibit the director or the chief of the Office of the Consumer Advocate from affirmatively approving a proposed rule, regulation, or fee change at any time within the 30-day period after it has been submitted to him or her, in which event it shall become effective upon compliance with this section and the procedures required by Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 18. Section 321 of the Business and Professions Code is amended to read:

321. Whenever it appears to the director or the chief of the Office of Consumer Advocate that the interests of the consumers of this state are being damaged, or may be damaged, by any person who engaged in, or intends to engage in, any acts or practices in violation of any law of this state, or any federal law, the director or any officer or employee designated by the director, or the Attorney General, may commence legal proceedings in the appropriate forum to enjoin those acts or practices and may seek other appropriate relief on behalf of those consumers.

SEC. 19. Chapter 4.5 (commencing with Section 360) is added to Division 1 of the Business and Professions Code, to read:

CHAPTER 4.5. OFFICE OF THE CONSUMER ADVOCATE

Article 1. General Provisions

360. This chapter shall be known and may be cited as the Office of the Consumer Advocate Act.

361. It is the intent of the Legislature and the purpose of this chapter to promote the efficiency of each of the boards that comprise the department by ensuring that each board properly discharges its regulatory and disciplinary functions to protect the interests of consumers.

362. The following definitions apply for purposes of this chapter:

(a) "Board" means any entity listed in Section 101.

~~(b) "Chief" means the chief of the Office of the Consumer Advocate.~~

~~(c) "Interests of consumers" means the protection of the health, welfare, and safety of consumers by a board.~~

~~(d) "Office" means the Office of the Consumer Advocate.~~

~~Article 2. Administration~~

~~370. The Office of the Consumer Advocate is hereby established in the department.~~

~~371. The office is under the supervision and control of a chief. The chief shall be appointed by the Governor, subject to confirmation by the Senate pursuant to Section 1322 of the Government Code. The chief shall be appointed for a term of four years. Upon expiration of the chief's term, the chief shall continue to serve in the position until a new chief is appointed by the Governor. The director shall fix the amount of the chief's compensation in accordance with law. The Governor may remove the chief for any cause specified in Section 106.~~

~~372. The chief shall administer and enforce the provisions of this chapter. Every power granted or duty imposed upon the chief under this chapter may be exercised or performed in the name of the chief by an employee of the office, subject to any conditions and limitations the chief may prescribe.~~

~~373. (a) The chief, in accordance with the State Civil Service Act, shall appoint a chief counsel of the office and an adequate number of attorneys, as determined by the chief counsel, to carry out the provisions of this chapter.~~

~~(b) The chief, in accordance with the State Civil Service Act, may appoint and fix the compensation of clerical or other personnel as may be necessary to carry out the provisions of this chapter.~~

~~(c) All personnel appointed under this section shall perform their duties under the supervision and direction of the chief.~~

~~374. The chief may contract for the services of experts and consultants if necessary to carry out the provisions of this chapter and may provide compensation and reimbursement of expenses for those experts and consultants in accordance with state law.~~

~~Article 3. Powers and Duties~~

~~380. (a) The office shall serve as an independent monitor pursuant to Section 474.22.~~

~~(b) The office shall review interagency agreements pursuant to Section 102.3.~~

~~381. The chief may establish through regulations a Consumer Participation Program to allow the office to award reasonable advocacy and witness fees to any person or organization that has made a substantial contribution on behalf of the interests of consumers either through the adoption of a regulation by a board or through an order or decision issued by a board in a disciplinary proceeding.~~

~~382. The office may appear at a meeting of a board and shall be permitted to participate as an amicus curiae in disciplinary proceedings by the board whenever the chief determines that the appearance or participation is required to promote or protect the interests of consumers. The office shall conform with the provisions of the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) in discharging these duties.~~

~~383. The chief shall have the following powers and it shall be his or her duty to take the following actions:~~

~~(a) Recommend and propose the enactment of legislation that is necessary to protect and promote the interests of consumers.~~

~~(b) Represent the interests of consumers before federal and state legislative and regulatory hearings.~~

~~(c) Assist, advise, and cooperate with federal, state, and local agencies and officials to protect and promote the interests of consumers.~~

~~(d) Study, investigate, research, and analyze matters affecting the interests of consumers.~~

~~(e) Hold public hearings, subpoena witnesses, take testimony, compel the production of books, papers, documents, and other evidence, and call upon state agencies for information.~~

~~(f) Propose and assist in the creation and development of consumer education programs.~~

~~(g) Promote ethical standards of conduct for business, professions, and consumers related to the interest of consumers.~~